Preliminary outcome of Nellix-in-Nellix extensions in patients treated with failed endovascular aneurysm sealing

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ABSTRACT

Background: The 1-year results of the use of the Nellix (Endologix Inc, Irvine, Calif) endovascular aneurysm sealing (EVAS) device were initially promising. However, midterm complications including migration and aneurysm growth occurred more frequently than expected, which provided an incentive to refine the instructions for use. Strategies for the management of complications arising after endovascular aneurysm repair are often not applicable for EVAS, given the unique configuration of the Nellix device, and new techniques are needed. This study analyzes the clinical outcomes of both elective and emergency deployment of a new Nellix device within a primarily placed device, for failure of EVAS, which we refer to as a Nellix-in-Nellix application (NINA).

Methods: This is a global, retrospective, observational cohort study focusing on the early outcome of NINA for failed EVAS, including data from 11 European institutions and 1 hospital in New Zealand.

Results: A total of 41 patients were identified who underwent a NINA procedure. Of these, 32 (78%) were placed electively and 9 (22%) were placed on an emergency basis. Seven patients were initially treated with chimney EVAS (n = 5 in the elective NINA group and n = 2 in the emergency NINA group). The average time between the primary EVAS procedure and NINA was 573 days (interquartile range, [IQR] 397-1078 days) and 478 days (IQR, 120-806) for the elective and emergency groups, respectively. The indication for elective NINA was endoleak with migration (50%), endoleak without migration (25%), migration without endoleak (16%), and other (9%). Chimney grafts were used in 21 of 32 patients in the elective group and 3 of 9 patients in the emergency group. Technical success was achieved in 94% of patients in the elective group and 100% of patients in the emergency group. At latest follow-up (median, 104 days; IQR, 49-328 days), there were three aneurysm-related deaths (9%), no ruptures, and five device-related reinterventions (16%) within the elective group. In the emergency group (median follow-up, 23 days; IQR, 7-61 days), there were four aneurysm-related deaths and three aneurysm-related reinterventions.

Conclusions: In conclusion, a NINA can be used to treat late failures of EVAS with an acceptable technical success rate and can be used when more established treatment options are unfeasible or contraindicated. The durability of this technique needs to be further reviewed. (J Vasc Surg 2019;70:1099-106.)

Keywords: Abdominal aortic aneurysm; Endovascular aneurysm sealing; Endovascular aneurysm repair; Vascular surgery

After the introduction of endovascular aortic aneurysm repair (EVAR) stent graft designs and delivery systems have continued to evolve.[1] EVAR has replaced open repair as the most common treatment option for an abdominal aortic aneurysm (AAA)[2] owing to decreased early morbidity and mortality.[3-5] EVAR, however, has

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anatomic limitations and reinterventions after EVAR are common, costly, and often complex.

The Nellix (Endologix Inc, Irvine, Calif) endovascular aneurysm sealing (EVAS) system, commercially introduced in 2013, presented a new approach to aneurysm exclusion with the use of a sac-anchoring endograft in an attempt to decrease the complication and reintervention rates. EVAS was designed to completely fill the aneurysm sac and, as such, decrease the incidence of endoleaks. The published early results with the Nellix system have shown a high technical success with variable complication rates.[6,7] The 2-year results of the EVAS FORWARD IDE trial revealed a 6.0% incidence of migration leading to a dedicated root-cause analysis, resulting in refinements to anatomic indications within the instructions for use (IFU) by proximal diameter constraints and limitations regarding the amount of thrombus within the aneurysm.[8]

Regular management strategies of complications as performed for late failure of EVAR, including stent graft extensions, are not suitable after EVAS and alternatives are therefore necessary.[9] In particular, type IA endoleaks and stent graft migration necessitated novel and endovascular solutions, especially because conversion to open repair carries an extensive burden on the patient. The use of a Nellix-in-Nellix application (NINA; Figs 1 and 2) to treat late failure of EVAS is not within the IFU, but could be a suitable treatment strategy for a type IA endoleak with or without migration. The technique and initial results of five revision cases have recently been described[10,11] and can be used both during the primary EVAS, in case of insufficient stent length, or as a revision strategy. Current research on EVAS has not evaluated the outcomes of NINA. Therefore, the objective of this study was to retrospectively analyze the clinical outcomes of the NINA performed for failed EVAS.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter, retrospective cohort study
- **Key Findings:** Using the Nellix-in-Nellix application for late failures of endovascular aneurysm sealing, the technical success rate was 94% in 32 elective repairs, with three aneurysm-related deaths and five device-related reinterventions at a median of 104 days. After nine emergency repairs, the technical success rate was 100%, with four aneurysm-related deaths and two aneurysm-related reinterventions at a median of 23 days.
- **Take Home Message:** The Nellix-in-Nellix application can be used when more established treatment options are not available, but durability needs further evaluation.

METHODS

Study design. This was a global, multicenter, retrospective observational study. A request for participation was sent to all centers that had performed 50 or more EVAS procedures from April 2013 to December 2016. There were 12 centers that had performed at least one Nellix-in-Nellix procedure and their cases were included. To be eligible for participation, a patient needed to have received a NINA as a revision after previous EVAS. No exclusion criteria were applied.

A case report form was completed by all centers individually and was based on hospital records and preoperative and postoperative imaging. Before data collection, each research site acquired approval by the local institutional review board according to national guidelines. Personal data were anonymized and handled in compliance with the Dutch Personal Data Protection Act (in Dutch, *Wet Bescherming Persoonsgegevens*). Study codes were used on the case report form and each participating site kept a separate document linking the study codes with the patients' identifying information. The study was conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, 2013) and in accordance with the applicable guidelines, regulations, and acts. Because retrospective patient file research does not fall under the scope of the Dutch Medical Research Involving Human Subjects act, informed consent was not required. All patient-related data were analyzed anonymously.

Procedural details. The details of a standard EVAS procedure have been previously described,[12] as well as the technical aspects of the NINA.[10] The latter differs in some aspects from a regular EVAS procedure. Briefly, the secondary Nellix device should protrude at least 30 mm above the primary stent to provide sufficient wall apposition of the endobags and achieve a seal. Care should be taken with the cannulation of the stent because the most distal stent is bare and can therefore complicate the cannulation. Ballooning of the primary Nellix device with a 12-mm balloon is recommended to maximize the lumen and create space for the fill-line of the secondary Nellix. Additionally, the endobags can be unfurled by performing a prefill of the endobags with saline solution with undeployed stents to get as much of the endobag as possible outside the primary Nellix stent, optimizing the wall apposition of the endobags. However, in revision cases it may be wise to refrain from the regular prefill phase, a crucial step during primary EVAS. When filling a proximal Nellix-in-Nellix extension, the required volume to reach the intended 180 mm Hg is often very small. In this situation, saline prefill may be counterproductive because the functional properties of the polymer change when more than 35% saline is mixed with polymer, which might occur when much of the prefill may not be

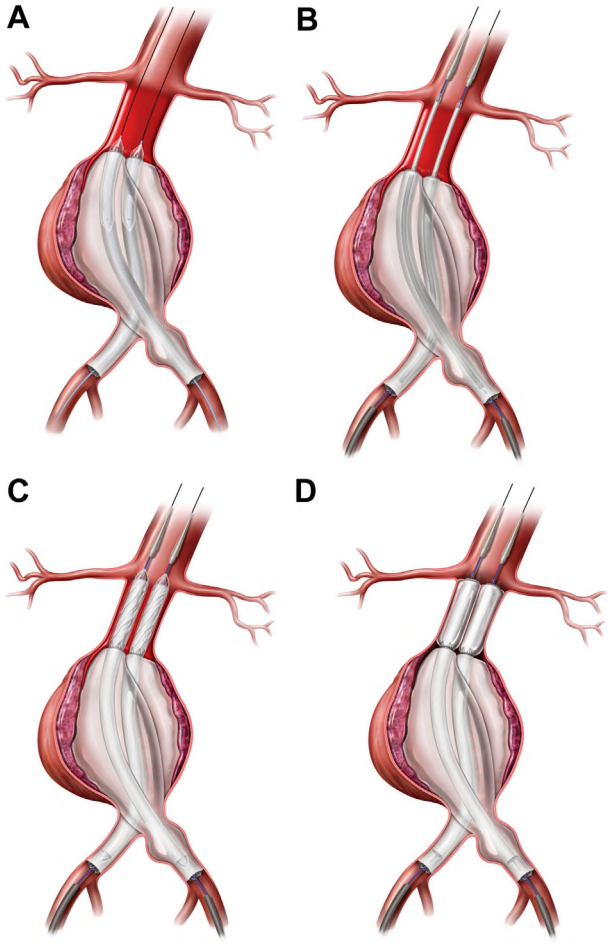

Fig 1. Procedure of placing a second Nellix stent graft into a previously placed Nellix. The devices are introduced into the primary Nellix stents **(A)**, the stents are positioned below the renal arteries **(B)**, after which they are deployed **(C)** and the Nellix balloons are inflated **(D)**.

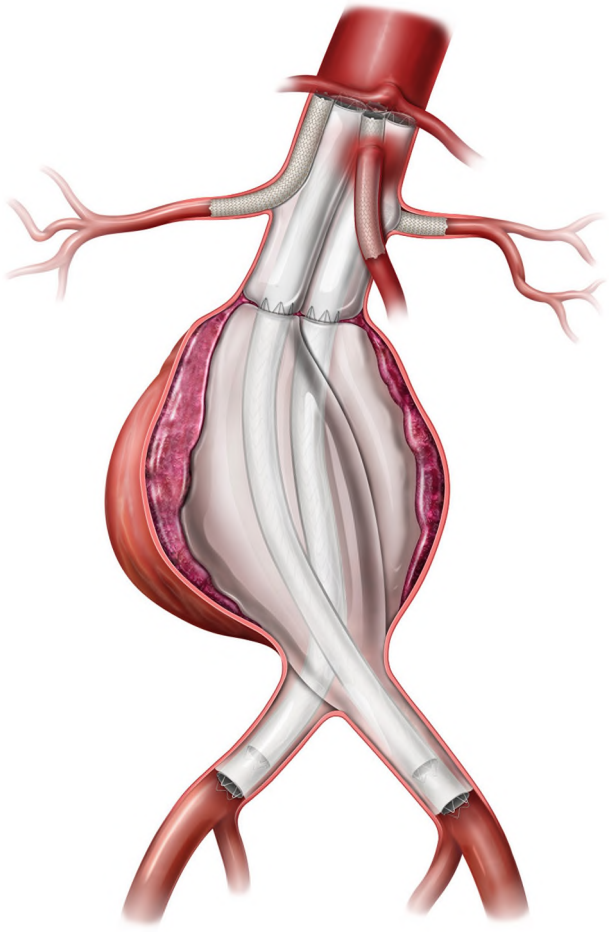

Fig 2. A Nellix-in-Nellix application (NINA) with concomitant chimney stents in the renal arteries and superior mesenteric artery.

aspirated. In contrast with primary EVAS, the Nellix balloons need to be deflated during endobag filling because pressurized Nellix balloons will interfere with the pressure measurements and give immediate high pressures. Additionally, because the distal part of the stent is uncovered, it is necessary to ensure that the wire is not behind the struts. A secondary fill can be performed at the discretion of the operator.[10]

End points. The main end points of this study were the technical success of NINA and frequency of reinterventions for the resolution of any AAA-related complication within 30 days after the NINA procedure or occurring after 30 days, but during the same hospital admission. The secondary study end point was to assess all clinical outcomes of patients undergoing this procedure including survival, aneurysm-related death, any type of complication, and aneurysm-related complications. An evaluation of the indication for the NINA was performed and attention was paid to the time interval between the primary and the secondary Nellix procedure and procedure information of both the primary and the secondary procedures. The end points were defined according to the reporting standards of the Society for Vascular Surgery.[11]

Comorbidities were scored according to the Society for Vascular Surgery comorbidity grading scale.[13] The patients were subdivided in groups for American Society of Anesthesiologists grade 2 and grade 2 or greater. Hypertension was defined as a known history of hypertension or use of antihypertensive medication. Hyperlipidemia was defined as a known history or the use of a statin or elevated lipid levels (low-density lipoprotein, total cholesterol, and triglyceride levels above normal limits for age). A patient was considered to have diabetes mellitus when there was a history of diabetes mellitus or use of an antidiabetic medication. Renal insufficiency was defined as a serum creatinine level of 2.4 mg/dL or higher or for a patient to be dependent of dialysis, either temporarily or chronically.[11]

Table I. Indication for late Nellix-in-Nellix application (*NINA*) placement

Indication	No. (%)
Device migration without endoleak	5 (12.2)
Device migration with endoleak	16 (39.0)
Endoleak without device migration	8 (19.5)
Endotension	2 (4.9)
Elective NINA for progressive CIA aneurysm	1 (2.4)
Acute AAA	9 (22.0)

AAA, Abdominal aortic aneurysm; *CIA*, common iliac artery.

Statistical analysis. Continuous variables were presented as mean and standard deviation or as median and interquartile range (IQR), depending on the distribution of the data. A normal distribution was determined by Kolmogorov-Smirnov tests and observation of histograms. Categorical variables were presented as frequencies and percentages. All statistical analysis were performed using IBM SPSS Statistics version 24.0 (IBM, Armonk, NY).

RESULTS

Included patients and indication for NINA. After requests for participation were sent out to 24 centers, a total of 12 centers responded by sending their data of NINA case(s). Overall, this study includes 41 cases of NINAs as revision after previous EVAS. The majority of cases (n = 32 [78.0%]) were treated in an elective setting for failure after EVAS. The indications for NINA are reported in Table I. Within the electively treated group, 21 of the 32 patients (66%) were treated for caudal migration of the stents, of which 13 had a type IA, 2 a type IB, and 1 a type III endoleak between the Nellix and a previously placed stent and five had no endoleak. Eight patients (25.0%) were treated for endoleak without migration, of which seven had a type IA and one patient had a type IA with a type II endoleak. Additionally, two patients received a NINA for endotension. There was one case of a common iliac artery aneurysm, which was already present during the first EVAS procedure but treated conservatively, because it was below the threshold for treatment. The diameter, however, progressed over time and reintervention was indicated. There were nine cases of NINA (22.0%) performed on an emergency basis, including six for ruptured AAAs and three for symptomatic but nonruptured AAAs.

Baseline characteristics and anatomy. Demographics and comorbidities of patients are reported in Table II. Anatomic characteristics before the primary EVAS are presented in Table III. Within the group of electively treated patients, the median AAA diameter at time of primary EVAS was 63 mm (IQR, 58-65 mm) with a luminal diameter of 38 mm (IQR, 30-43 mm). In the emergency group, the maximal AAA diameter was 62 mm (IQR, 51-76 mm), with a luminal diameter of 44 mm (IQR, 33-58 mm). Despite a median neck infrarenal length of 17 mm and 20 mm in the elective and emergency groups, respectively, a substantial heterogeneity was shown by the range of the neck length (7-26 mm in the elective group vs 3-36 mm in the emergency group).

Procedural characteristics of the primary EVAS procedure. Most patients underwent their primary EVAS procedure as an elective intervention (84.4% in the elective NINA group, 55.6% in the emergency NINA group).

Table II. Demographics and comorbidities before the first Nellix procedure

	Elective NINA	Acute NINA
Total No. of cases	32 (78.0)	9 (22.0)
Age at NINA procedure	75.0 ± 7.2	77.0 ± 8.9
Sex		
Male	25 (78.1)	6 (66.7)
Female	7 (21.9)	3 (33.3)
ASA class		
2	8 (25.0)	2 (22.2)
≥2	24 (75.0)	7 (77.8)
Diabetes mellitus	4 (12.5)	1 (11.1)
Smoking (current or in past 10 years)	19 (59.4)	3 (33.3)
Hypertension	29 (90.6)	6 (66.7)
Dyslipidemia	22 (68.8)	1 (11.1)
Cardiac disease	21 (65.6)	3 (33.3)
Renal insufficiency	10 (31.2)	2 (22.2)
Pulmonary disease	15 (46.9)	3 (33.3)

ASA, American Society of Anesthesiologists; *NINA*, Nellix-in-Nellix application.
Values are presented as number (%) or mean ± standard deviation.

Table III. Anatomic aorta characteristics before the first endovascular aneurysm sealing (EVAS) procedure

	Elective NINA	Acute NINA
Maximal AAA sac diameter, mm	63 (58-65)	62 (51-76)
Maximal AAA lumen diameter, mm	38 (30-43)	44 (33-58)
Maximal infrarenal neck diameter, mm	25 (23-31)	24 (23-28)
Infrarenal neck length, mm	17 (7-26)	20 (3-36)
Infrarenal neck angulation, mm	20 (10-46)	29 (6-47)
Maximal diameter left CIA, mm	16 (13-20)	18 (16-22)
Maximal diameter right CIA, mm	17 (13-24)	20 (16-26)
AAA type		
Fusiform	32 (100)	9 (100)
Saccular	0 (0)	0 (0)

AAA, Abdominal aortic aneurysm; *CIA*, common iliac artery; *NINA*, Nellix-in-Nellix application.
Values are presented as median (interquartile range) or number (%).

The remaining patients were primarily treated for a ruptured (6.3% in the elective NINA group, 33.3% in the emergency NINA group) or a symptomatic nonruptured aneurysm (6.3% in the elective NINA group, 11.1% in the emergency NINA group). There were four cases that were treated with a unilateral Nellix device in their primary EVAS procedure; all of these cases were in the group of elective NINA cases. In three cases, the first EVAS procedure consisted of revision of a failure of previous aortic surgery. Two patients had initially undergone an EVAR, but developed a secondary rupture treated with EVAS; one of these was in the emergency NINA cohort. The other patient previously underwent open aneurysm repair, but developed an anastomotic aneurysm treated by EVAS.

Within the primary EVAS group, there were seven chimney procedures (5 in the elective NINA group and 2 in the emergency NINA group) and 11 distal extensions were required (6 in the elective NINA group and 5 in the emergency NINA group). One concomitant procedure was performed during primary EVAS within the elective NINA group, which was a thrombectomy of the common femoral artery with patch. The remaining data from the primary EVAS procedure in patients who later received a NINA for late failure are given in Table IV.

Table IV. Procedural characteristics primary endovascular aneurysm sealing (EVAS) procedure of patients who later received a Nellix-in-Nellix application (*NINA*) for late failure

	Elective NINA	Acute NINA
Aneurysm symptomatology		
Asymptomatic	27 (84.4)	5 (55.6)
Symptomatic, nonruptured	2 (6.3)	1 (11.1)
Ruptured	2 (6.3)	3 (33.3)
Unknown	1 (3.1)	0 (0)
Unilateral Nellix device	4 (12.5)	0 (0)
Previous aortic intervention	2 (6.3)	1 (11.1)
Length right Nellix stent, mm	160 (150-180)	170 (155-180)
Length left Nellix stent, mm	160 (150-180)	180 (170-180)
Polymer volume, mL	72 (60-120)	115 (95-130)
Polymer pressure, mm Hg	180 (180-193)	193 (180-220)
Procedural time, minutes	110 (92-140)	120 (105-141)
Postprocedural endoleak	2 (6.3)	1 (11.1)

Values are presented as number (%) or median (interquartile range).

Procedural characteristics NINA procedure. The median time between primary EVAS and NINA for late failure was 573 days (IQR, 397-1078 days) within the elective group and 478 days (IQR, 120-806 days) within the emergency group. Most patients underwent a bilateral NINA procedure (84.4% in the elective group, 77.8% in the emergency group) but some patients received a unilateral extension (5 in the elective group and 2 in the emergency group), of which five were distal NINA extensions. The median length of the Nellix stent used was 100 mm (IQR, 100-120 mm) for both groups and both sides. Most Nellix devices were placed proximal to the first Nellix device (91.5% in the elective group and 87.5% in the emergency group). Indications for distal Nellix placement were type IB endoleak (n = 4) in one case combined with rupture, common iliac artery aneurysms (n = 2) and rupture of an aneurysm of the external iliac artery (n = 1).

The median amount of polymer volumes used were 15 mL (IQR, 11-30 mL) and 8 mL (IQR, 5-19 mL) for the elective and emergency groups, respectively, and in the minority of cases a secondary fill was performed (25.0% within the elective group, 11.1% within the emergency group). Overall, the procedure lasted a median of 208 minutes (IQR, 164-256) minutes in the elective group and 102 minutes (IQR, 70-304 minutes) in the emergency group. There were two cases of technical failure (both in the elective group; none in emergency group), one because of a postoperative endoleak type IA and one intraoperative endobag rupture. The technical success rates were 93.8% and 100% in the elective and emergency cohorts, respectively. Procedural characteristics of the NINA procedure for the patients can be found in Table V.

Thirty-day/in-hospital outcome elective NINA. Within the elective NINA group, there was one death caused by multiple organ failure after conversion for an intraoperative endobag rupture. Additionally, one patient experienced upper gastrointestinal bleeding on the same day as the NINA procedure with a subsequent lengthy intensive care stay. Eventually, this patient died owing to cardiorespiratory insufficiency 47 days after the NINA procedure. Seven patients (21.9%) required a reintervention within 30 days. There was one case of postoperative type IA endoleak, successfully embolized after 21 days. One patient had thrombosis of a chimney graft successfully treated with percutaneous aspiration thrombectomy and relining with full recovery of renal function. There were two access-related reinterventions. Finally, two patients developed a compartment syndrome of the lower limb and underwent a fasciotomy, after 1 and 3 days. Another patient was converted to an open repair 2 weeks after NINA; postoperative angiography showed polymer leakage without immediate sequelae, but computed tomography angiography on follow-up confirmed polymer bulging and also showed a small type IA endoleak.

There were six (18.8%) conservatively treated complications, including one postoperative type II endoleak and one inguinal hematoma. There were two arterial thromboses treated with heparin, both with a successful outcome; one of these patient had right leg ischemia secondary to occlusive thrombus in the right popliteal

Table V. Procedural characteristics Nellix-in-Nellix application (*NINA*) procedure of patients who received the NINA for late failure

	Elective NINA as revision	Acute NINA as revision
Time from primary EVAS to NINA, days	573 (397-1078)	478 (120-806)
Access type		
Cutdown	21 (65.6)	5 (55.6)
Percutaneous	10 (32.3)	4 (44.4)
Both	1 (3.1)	0 (0)
Anesthesia type		
General	31 (96.9)	9 (100)
Missing	1 (3.1)	0 (0)
Unilateral NINA		
Left	3 (9.4)	1 (11.1)
Right	2 (6.3)	1 (11.1)
Bilateral Nellix device	27 (84.4)	7 (77.8)
Length right Nellix stent	100 (100-120)	100 (100-120)
Length left Nellix stent	100 (100-120)	100 (100-120)
Location		
Proximal NINA	54 (91.5)	14 (87.5)
Distal NINA	5 (8.5)	2 (12.5)
Prefill, mL	28 (87.5)	8 (88.9)
Polymer volume, mL	15 (11-30)	8 (5-19)
Polymer pressure, mm Hg	200 (190-240)	190 (180-200)
Secondary fill, mL	8 (25.0)	1 (11.1)
Distal extension	5 (15.6)	1 (11.1)
Chimney procedure	21 (65.6)	3 (33.3)
Total procedure time, minutes	208 (164-256)	102 (70-304)
Estimated blood loss, mL	350 (200-700)	200 (100-700)
Postprocedural endoleak	2 (6.3)	1 (11.1)
Technical success	30 (93.8)	9 (100)

EVAS, Endovascular aneurysm sealing.
Values are presented as number (%) or median (interquartile range).

artery and the other patient had partial thrombosis of both femoral arteries. One patient had an ischemic stroke, 1 day after NINA, that was treated with thrombolysis; however, symptoms persisted. Finally, one patient with gastrointestinal bleeding has been described elsewhere in this article.

Outcome at latest follow-up elective NINA. The median follow-up after elective NINA was 3 months (IQR, 1-11 months). Between 30 days or hospital discharge and the latest follow-up five deaths occurred (15.6%), of which one (3.1%) was aneurysm related. This patient developed multiple organ failure as a result of a suspected graft infection 10 months after NINA and refused further treatment. The remaining patients died of cardiorespiratory insufficiency (683 days after NINA), pneumonia (52 days after NINA), advanced age (69 days after NINA), and type A aortic dissection (103 days after NINA). Two patients (6.3%) underwent a reintervention between 30 days and latest follow-up, including stenting of the Nellix for a stenosis 74 days after NINA, and embolization of a type IA endoleak 19 months after NINA.

Between 30 days and the latest follow-up, five patients (15.6%) had a conservatively treated complication, and three of these (9.4%) patients had already experienced a complication within 30 days. Complications included two distal migrations of the stent graft at 11 and 6 months without endoleak, which were both treated conservatively. Additionally, there was one persisting type II endoleak with a stable aneurysm sac diameter. One patient had a type IB endoleak 1 month after NINA, left owing to the serious clinical condition of the patient; this patient later experienced an embolic renal infarction. One fracture of a Nellix stent graft was treated conservatively.

Thirty-day/in-hospital outcome for emergency NINA. Among the group of patients who underwent an emergency NINA after a primary EVAS procedure, there were four deaths (44.4%) within 30 days or during their hospital stay. One patient died 1 day after NINA owing to multiple organ failure. One patient died 6 days after the procedure of acute renal failure and blood results showing high C-reactive protein levels and leukocyte counts, despite hydration therapy and broad-spectrum antibiotic therapy. Another patient suffered a major cranial bleeding that led to her death 11 days after NINA. Finally, one patient underwent laparotomy to decompress a large retroperitoneal hematoma and died 7 days after the NINA procedure owing to extensive neurologic deterioration with cerebral damage. This was also the only reintervention within 30 days within this group.

There was one conservatively treated complication (11.1%). This patient had a thrombosis of the left Nellix stent graft.

Outcome at latest follow-up of emergency NINA. Within the emergency NINA group, the median follow-up was 23 days (IQR, 7-191 days). There were no patients within this group who died between 30 days and the latest follow-up. However, two (22.2%) additional device-related reinterventions were performed. One patient developed a thrombosis of the Nellix system for which thrombectomy and angioplasty was performed after 2 months (63 days) with a good result. Another patient had a stenosis of the right Nellix limb causing intermittent claudication, and was treated successfully with right iliac angioplasty after 4 months. Apart from these complications, no other complications in this patient group were reported.

DISCUSSION

The current study has shown the feasibility of NINA for late failure of EVAS with an overall technical success rate of 95.1%. However, this is a preliminary report, because

less than 25% of cases had a follow-up of more than 1 year and in the emergency group more than 75% had a follow-up of less than 2 months; as such, these results must be interpreted with care. There was one procedural type IA endoleak that was treated successfully. The other patient with technical failure died owing to multiple organ failure after intraoperative rupture of the endobag. Little is known about endobag rupture during EVAS and the potential effects of polymer to the body. One comparable case is previously published,[14] showing a patient who underwent an EVAS procedure for an anastomotic aneurysm resulting in rupture and displacement of polymer material causing peripheral ischemia and renal and visceral occlusion. After removal of the filling material by open surgery, the patient completely recovered. As observed in the present study, the amount of required polymer volume during NINA is extremely small. This factor relates to very steep volume-pressure curve that easily may cause high pressures in the endobag, potentially leading to prolapse or rupture of the endobag. This case emphasizes that the filling of the endobags in these cases should be performed slowly and with care.

It is notable to mention that the infrarenal neck length before the first EVAS had a large IQR (7-26 mm in the elective group and 3-36 mm in the emergency group) and that chimneys were already used during primary EVAS in seven cases. The IFU states that the proximal neck length should be greater than 10 mm, but most patients in this cohort did not meet with this requirement. Thompson et al[15] showed that patients treated within the IFU have fewer complications and reinterventions after EVAS, but the refined IFU has significantly reduced applicability of EVAS,[9] leading to the fact that fewer patients are candidates for the Nellix graft. Nevertheless, with these refinements we previously observed a decrease in the migration and reintervention rates. Our data did not include all IFU characteristics and as such we could not present the number of patients treated outside of IFU in their primary Nellix procedure.

For most patients, the second Nellix stent was implanted proximal to the first Nellix stent and a short stent (median, 100 mm) was used. Repeat failure after NINA remains as a risk and as such these patients require follow-up with computed tomography scans. Migration of the Nellix stents is likely to be related to a large aneurysm volume in combination with a small flow volume, as reflected in the latest IFU. In these cases, laterally working distraction forces may lead to bowing of the stents and result in migration.[16] Our approach now has evolved to use the longest possible Nellix stents, to stiffen the entire reconstruction, ensuring stability and potentially preventing remigration.

As previously described, the technique of NINA significantly differs from primary EVAS.[10,17] Predilation of the stents with a 12-mm balloon is advocated to prevent a crush of the fill line and to provide more space for the secondary Nellix stents. During the filling phase, the Nellix balloons should be deflated to prevent false high pressure measurement and potential endobag damage and rupture. The steep volume-pressure curve has been discussed elsewhere in this article, but the small volume may also cause other problems. After prefilling with saline solution, usually 3-5 mL remains in the endobags.[10] With small polymer volumes, the dilution by the remaining prefill might pose a problem for polymerization. In this cohort, the majority of patients did, however, receive a prefill despite the use of a small polymer volume and without reported complications. Notably, the fill pressure in the NINA procedure was higher than seen in a regular Nellix procedure.

Considering the short duration of follow-up and small cohort, the results of this study should be interpreted with care. This study shows that the NINA procedure is technically feasible; however, the efficacy of the procedure remains to be determined. Most of the patients in this study received NINA for migration with loss of seal or impending loss of seal and, in these cases, a conversion to open repair would have been a more established treatment option. The absence of suprarenal fixation may even render conversion to open surgery less complicated when compared with EVAR and, thus, more attractive. The NINA procedure could be indicated when more established treatment options are unfeasible or contraindicated, because many patients do not meet the requirements for open repair, mainly owing to old age and comorbidities. In cases of migration with type IA endoleak but adequate seal, embolization or relining with stiff stents remain an option.[18]

During our follow-up period, there were three aneurysm-related deaths within the elective and the emergency groups and a reintervention rate of 22% within 30 days. Our study group was heterogeneous, with both elective and emergently treated patients and with both regular and complex neck anatomies. Data in the current study were site reported, and there is a risk for a selection bias. As discussed, the NINA strategy may have been chosen over open conversion owing to the clinical state or age of the patient, which could provide an explanation for the high morbidity rate. It is evident that this procedure was challenging; more than 65% of the patients in the elective group required one or more chimneys in addition to the NINA to achieve a proper seal zone and 7 of 41 patients (17%) had primary chimney EVAS. Moreover, another four patients (10%) were primarily treated with a single Nellix stent, also suggesting a complex anatomy. Additionally, within the emergency group, 33% were treated with NINA for a re-rupture of the aneurysm. Owing to our highly heterogeneous and challenging cohort, it is difficult to compare our time to reintervention after EVAR.

CONCLUSIONS

A NINA can be used to treat late failures of EVAS with an acceptable technical success rate and can be used when more established treatment options are unfeasible or contraindicated. The durability of this technique needs to be further evaluated given the short follow-up available to date.

AUTHOR CONTRIBUTIONS

Conception and design: AZ, CZ, MR
Analysis and interpretation: AZ, CZ, MR
Data collection: AZ, SZ, JH, JV, AO, TK, PB, KS, IL, FT, PS, EZ, AH, AH-D, MR
Writing the article: AZ
Critical revision of the article: AZ, SZ, CZ, JH, JV, AO, TK, PB, KS, IL, FT, PS, EZ, AH, AH-D, MR
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