Combining Endovascular Aneurysm Sealing with Chimney Grafts – 5 Year Follow-Up after 47 Procedures

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Background: To evaluate longer-term results of a cohort treated with primary chimney endovascular aneurysm sealing (ChEVAS) for complex abdominal aortic aneurysms or secondary ChEVAS after failed endovascular aneurysm repair/endovascular aneurysm sealing.

Methods: A single-center study was conducted of 47 consecutive patients (mean age 72 ± 8 years, range 50–91; 38 men) treated with ChEVAS from February 2014 to November 2016 and followed through December 2021. The main outcome measures were all-cause mortality (ACM), aneurysm-related mortality, occurrence of secondary complications and conversion to open surgery. Data are presented as the median (interquartile range [IQR]) and absolute range.

Results: 35 patients received a primary ChEVAS (=group I) and 12 patients a secondary ChEVAS (=group II). Technical success was 97% (group I) and 92% (group II); 30-day mortality was 3% and 8%, respectively. The median proximal sealing zone length was 20.5 mm (IQR 16, 24; range 10–48) in group I and 26 mm (IQR 17.5, 30; range 8–45) in group II, respectively. During a median time of follow-up of 62 months (range 0–88), ACM amounted to 60% (group I) and 58% (group II); aneurysm mortality was 29% and 8%, respectively. An endoleak was seen in 57% (group I: 15 type Ia endoleaks, four isolated type Ib, and 1 endoleak type V) and 25% (group II: 1 endoleak type Ia, one type II, and 2 type V), aneurysm growth in 40% and 17%, migration in 40% and 17%, resulting in 20% and 25% conversions in group I and II, respectively. Overall a secondary intervention was performed in 51% (group I) and 25% (group II), respectively. The occurrence of complications did not significantly differ between the 2 groups. Neither the number of chimney grafts, nor the thrombus ratio significantly affected the occurrence of abovementioned complications.

Conclusions: While initially delivering a high technical success rate, ChEVAS fails to provide acceptable longer-term results both in primary and secondary ChEVAS, resulting in high rates of complications, secondary interventions and open conversions.

INTRODUCTION

Even after years of innovation, the most suitable treatment of complex abdominal aortic aneurysms (AAA) remains a highly individual decision and a field of great controversy.[1–7] This is due to various endovascular treatment options including but not limited to fenestrated and branched endovascular

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aneurysm repair (fEVAR and bEVAR), as well as chimney-EVAR.[8] Since all abovementioned techniques are continuously refined and pushed forward, it comes as no surprise that it was only a matter of time until a new concept such as the endovascular aneurysm sealing (EVAS) system Nellix (Endologix, Irvine, CA) would enter the stage of complex AAA repair.[9–14] The benefits of combining EVAS with chimney grafts seemed obvious: While preserving the advantages of an ''off-the-shelf'' solution, the sealing of the aneurysm sac might have the potential to take care of the Achilles' heel of ChEVAR, namely gutter formation and consequent type Ia endoleak.[15]

Early results of chimney endovascular aneurysm sealing (ChEVAS) (and EVAS) were promising, however, later reports revealed higher than anticipated rates of endoleaks, migrations and aneurysm growth, which eventually led to the voluntary withdrawal of the device in 2019.[15–19]

Even more surprisingly, the U.S. Food and Drug Administration just recently granted a Breakthrough Device Designation to Endologix for a new study combining the Nellix 3.5 with parallel visceral stents; the first (early) results of the sponsored chEVAS 1 trial have already been published, reporting a 100% technical success rate in 4 patients, with a follow-up of 6 weeks for 2 patients and 6 months for the remaining 2.[20]

Since previous publications regarding the durability of ChEVAS are sparse and limited to only mid-term follow-up, the current study presents 5-year follow-up of 47 patients treated with primary ChEVAS for complex AAA or secondary ChEVAS after failed EVAR/EVAS, resembling a real world experience with the benefits of being an independent, nonindustry sponsored trial.[16,18,21] It focuses on all-cause mortality (ACM), aneurysm-related mortality (ARM), occurrence of secondary complications (endoleak, migration, aneurysm growth and rupture) and conversion to open surgery. Results of primary and secondary ChEVAS are separately analyzed and then compared to 1 another with the goal of shedding light on the understanding of the underlying mechanisms leading to failure after chimney EVAS, as well as discussing possible ways of dealing with ChEVAS complications.

MATERIALS AND METHODS

Combining Chimneys With EVAS (ChEVAS)

The technique of ChEVAS has previously been described and published.[9–15] In summary, upper limb access was usually gained through a conduit to the left axillary artery, allowing simultaneous introduction of multiple sheaths for cannulation and delivery of the chimney stent-grafts, without damaging the artery wall with every additional puncture/sheath. Both balloon-expandable stent-grafts (including E-ventus BX (Jotec, Hechingen, Germany), Atrium Advanta V12 (Atrium Maquet Getinge Group, Mijdrecht, the Netherlands) and self-expanding stent-grafts (Viabahn (W.L. Gore & Associates, Flagstaff, AZ, USA) were used, depending on both anatomic circumstances (self-expanding for elongated, curved target vessels and balloon-expandable for rather straight target vessels) and surgeons' personal preference. After chimney-graft placement, the Nellix stent-grafts were placed through a femoral access via bilateral cut-down. During the prefill and polymerization phase, balloon-expandable chimney-grafts were protected with ballooning, while in cases with self-expandable stent-grafts, the Nellix stents were deployed first, followed by withdrawal of the protective sheaths allowing full expansion of the chimney-grafts.[15]

The procedures took place in a hybrid operating room equipped with an Artis Zeego (Siemens AG, Munich, Germany) and were performed under general anesthesia. A first postoperative CT scan was done before discharge; follow-up surveillance included contrast-enhanced ultrasound at 3 and 6 months and CT scans at 12 months and annually thereafter.

Intraoperatively, all patients received unfractionated heparin with the goal of an activated clotting time of 200–250 sec; postoperatively they received a dual platelet aggregation inhibition therapy with Aspirin and Clopidogrel for 8 weeks and a mono platelet inhibition therapy thereafter.

Study Design

The single-center study retrospectively enrolled 47 consecutive patients (mean age 72 ± 8 years, range 50–91; 38 men) who received a primary ChEVAS procedure ($n = 35$) for the treatment of complex AAA, or a secondary ChEVAS procedure ($n = 12$) for the treatment of failed EVAR ($n = 7$) or failed EVAS ($n = 5$) from February 2014 until November 2016. Before the first ChEVAS procedure was carried out, 21 standard EVAS procedures had been performed. The cohort was followed through December 2021. It included both elective and symptomatic cases; ruptured aneurysms were excluded. The local ethics committee waived the need to obtain consent for the collection, evaluation, and publication of the retrospectively collected and anonymized data used in this analysis (ethics approval #2017–21).

Definitions and Statistical Analysis

Procedures were assessed as technically successful when the stent-graft delivery resulted in complete sealing without type I or III endoleak or the need of conversion to open surgery. The events of primary interest included technical success, as well as early and late mortality. Events of secondary interest covered all procedure-related or device-related complications (endoleak, migration, aneurysm growth, aneurysm rupture and limb/chimney occlusion, etc.). Migration was defined as any stent-graft movement of 4 mm related to a predefined reference vessel or any migration leading to an endoleak.[22] Sealing zones were reported as defined by Fillinger et al. in the Society of Vascular surgery classification.[15,23] The length of the proximal sealing zone was estimated as the distance between the second most proximal stent row of the Nellix stent-graft (i.e. the approximate beginning of the endobags) and the distal end of the proximal aneurysm neck (in cases of primary ChEVAS) or the most proximal portion of the previously implanted stent-grafts (in cases of secondary ChEVAS), respectively.

Continuous data are given as the means ± standard deviation or median [interquartile range: Q1, Q3]; categorical data are presented as the counts (percentage). Nominal variables were analyzed using the Fisher exact test, while numeric variables were compared with the Mann-Whitney *U* test due to the mostly not normal distribution. To estimate survival, freedom from endoleak and/or migration, and freedom from reintervention, the Kaplan-Meier method was applied. A comparison of the curves was done using the log-rank test. Outcomes are given as the odds ratio (OR) and 95% confidence interval (CI). The threshold of statistical significance was set to $P < 0.05$. Statistical analyses were performed using StatsDirect (version 3.1.8; StatsDirect Ltd, Altrincham, UK).

RESULTS

Patient demographics and anatomical characteristics are shown in Table I and Table II, respectively.

On average, 2 chimney-grafts were used per patient (103 grafts in total); 86 (83%) had a balloon-expandable design and 17 (17%) a self-expanding design. Figure 1 gives an overview of the number of target vessels treated with chimney grafts within the groups of primary and secondary ChEVAS, and the associated sealing zones, respectively. The median proximal sealing zone length was 20.5 mm (interquartile range [IQR] 16, 24; range 10–48) for primary ChEVAS and 26 mm (IQR 17.5, 30; range 8–45) for secondary ChEVAS, respectively.

Early Outcomes

The technical success was 97% (34/35) due to a small endoleak type Ib (which was not corrected in the initial procedure and required no further interventions during follow-up) in the group of primary ChEVAS procedures, and 92% (1/12) attributed to 1 case of a low flow gutter endoleak type Ia in the group of secondary ChEVAS procedures. 30-day mortality was 3% (1/35) in the group of primary ChEVAS: the patient developed an acute kidney failure, which was attributed to an early chimney graft thrombosis of the right renal artery 2 days postoperatively. Even though an interventional recanalization of the chimney graft was successfully performed, the patient later developed multisystem organ failure (MOV) and died 28 days after the index procedure. In the group of secondary ChEVAS, 30-day mortality was 8% (1/12) due to a fatal intracranial hemorrhage 27 days after surgery.

Late Outcomes

Mortality. Over a median follow-up of 62 months (range 0–88), the ACM for the patients treated with primary ChEVAS amounted to 60% (21/35). ARM was 29% (10/35): Aside from the abovementioned early death due MOV, four patients died from aneurysm rupture, while 5 patients developed MOV (2 after open conversion, 1 after Nellix limb and chimney graft thrombosis, 1 after intraoperative endobag rupture for treatment of an endoleak type Ib, and 1 after Nellix limb thrombosis in a palliative setting, respectively).

The cancer-related mortality (CRM) was 11% (4/35), while other causes amounted to 11% (4/35) and unknown in 9% (3/35). For the patients treated with secondary ChEVAS (median follow-up 62 months, range 0–82) ACM was 58% (7/12), ARM was 8% (1/12; attributed to aforementioned fatal intracranial hemorrhage 27 days after the index procedure) and CRM was 17% (2/12), respectively. Two patients died of other causes and 2 patients of unknown causes.

The freedom from ACM was 85% at 1 year, 74% at 2 years and 50% at 5 years. The freedom from ARM was 93% at 1 year, 88% at 2 years and 73% at 5 years, respectively. Both sealing zones and reconstruction type had an impact on ACM, which was however not significant. Survival estimates for

Table I. Patient demographics and comorbidities[a]

Patient data	Primary ChEVAS $n = 35$	Secondary ChEVAS $n = 12$
Patient characteristics		
Age, y	70 (56−84)	76 (50−91)
Men	29 (83)	9 (75)
Comorbidities		
BMI >30 kg/m2	7 (20)	4 (33)
Hypertension	29 (83)	11 (92)
CAD	12 (34)	4 (33)
Arrhythmia	3 (9)	3 (25)
Valvular heart disease	4 (11)	1 (8)
CABP	5 (14)	0
COPD	11 (31)	2 (17)
Stroke	8 (23)	1 (8)
PVD	6 (17)	3 (25)
Diabetes	5 (14)	3 (25)
Smoking (≤ 10 years)	7 (20)	3 (25)
Smoking current	15 (43)	1 (8)
Renal insufficiency[b]	12 (34)	5 (42)
Hyperlipidemia	20 (57)	7 (58)
Abdominal surgery/trauma	3 (9)	6 (50)
ASA		
I	0	0
II	11 (31)	1 (8)
III	22 (63)	10 (83)
IV	2 (6)	1 (8)
V	0	0

ASA, American Society of Anesthesiologists; BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PVD, peripheral vascular disease; CABP, coronary artery bypass.

[a]Continuous data are presented as the median (range); categorical data are given as the counts (percentage).

[b]Creatinine >2.0 mg/dL.

patients according to seal zone (i.e. 8, 7, and 6) were 88%, 70% and 100% at 1 year, 80%, 60% and 0% at 2 years and 54%, 40% and 0% at 5 years, respectively. Note: only 1 case with seal zone 6. Correspondingly, the survival estimates for patients according to reconstruction type (i.e. 1, 2, 3, and 4 target vessels) were 89%, 85%, 63%, and 100% at 1 year, 67%, 81%, 63%, and 50% at 2 years, and 44%, 59%, 38%, and 0% at 5 years, respectively. Figure 2 A displays the Kaplan-Meier curve for the cumulative survival rate after primary and secondary ChEVAS. Please note that in the group of secondary ChEVAS, 1 patient was lost to follow-up.

Endoleaks, migrations, aneurysm growth, and ruptures. In the group of primary ChEVAS, a total of 20 (57%) patients developed an endoleak: 15 type Ia endoleaks, four isolated type Ib and 1 endoleak type V (endotension with aneurysm growth). There was no endoleaks type II. Of all endoleaks, only abovementioned endoleak type Ib was identified within 30 days, while all others were late endoleaks (median time post implantation 35 months, range 1−78). EVAS migration occurred in 14 (40%) patients and in all cases an endoleak was present. Accordingly, a total of 20 (57%) patients were affected by the event endoleak and/or migration. Aneurysm growth and rupture were seen in 14 (40%) and 7 (20%) cases, respectively.

In the group of secondary ChEVAS, four (33%) patients had an endoleak: 1 early (aforementioned) endoleak type Ia, 1 type II, and 2 type V, respectively. Since the endoleak type II did not affect the ChEVAS procedure, but rather the previously implanted EVAR device, it was not counted as ChEVAS associated. The endoleaks occurred a median time of 7 months post implantation, (range 3−17). Migration was found in 2 patients (both had received a secondary ChEVAS procedure as a repair after EVAS) and aneurysm growth occurred in 2 cases (1 after EVAS and 1 after EVAR repair, respectively).

Figure 2 B displays the Kaplan-Meier curves for the cumulative freedom from endoleak and/or

Table II. Anatomical Characteristics of the Aneurysms treated with primary and secondary Chimney Endovascular Sealing (ChEVAS)

Characteristics	Primary ChEVAS $n = 35$	Secondary ChEVAS $n = 12$
Aneurysm diameter (mm)	57,5 [52–62] (47–86)	75,5 [62–92] (50–121)
Proximal neck diameter (mm)	28 [25–34] (20–46)	26 [24–30] (22–36)
Proximal neck length (mm)	0 [0–7] (0–24)	0 [0–0] (0–12)
Proximal neck angulation (°)	23,5 [15–32] (0–70)	24,5 [22–40] (0–83)
Right common iliac artery diameter (mm)	15 [13–26] (10–32)	19,5 [18,5–22] (10–36)
Left common iliac artery diameter (mm)	15 [12–20] (10–38)	18 [15,5–22,5] (10–46)
Right common iliac artery length (mm)	40 [28–54] (15–82)	27 [20–47] (18–59)
Left common iliac artery length (mm)	45 [38–54] (17–80)	18 [17–53] (17–67)
Thrombus ratio	1.48 [1.24–1.73] (1.04–2,28)	-

Median [interquartile range Q1, Q3] (absolute range).

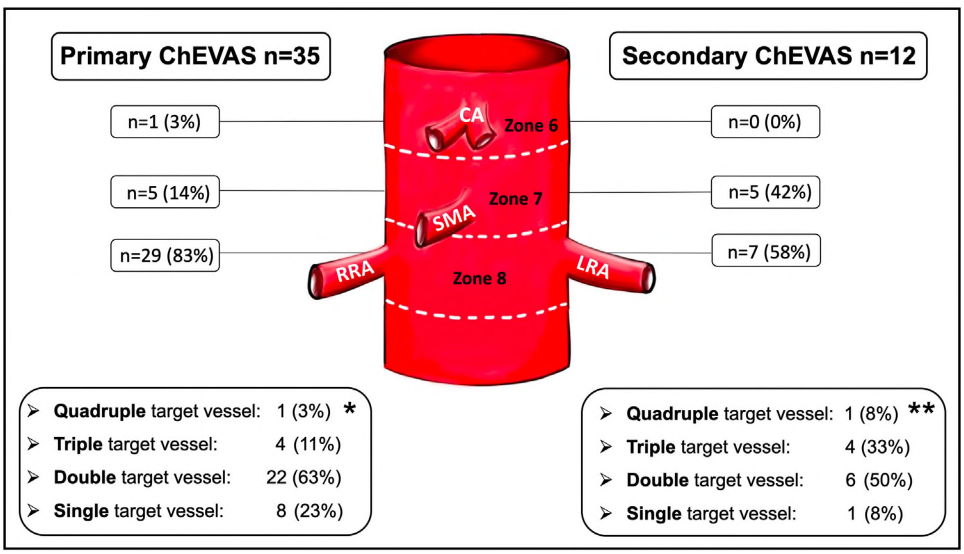

Fig. 1. Overview of the number of target vessels within the groups of primary and secondary Chimney Endovascular Aneurysm Sealing (ChEVAS) and the associated sealing zones. CA, celiac artery; LRA, left renal artery; RRA, right renal artery; SMA, superior mesenteric artery. *One case of a double target vessel ChEVAS resulted in a zone 7 sealing, because the patient had just 1 renal artery. * The 1 quadruple target vessel ChEVAS resulted in a zone 7 sealing, because the patient had 2 left renal arteries and hence received 3 renal chimneys and 1 mesenteric chimney.

migration. At 1, two, and 5 years the estimates were 86% (95% CI 75% to 95%) 75% (95% CI 61% to 88%) and 36% (95% CI 19% to 53%), respectively. Figure 3 demonstrates a case of massive migration, endoleak type Ia and aneurysm growth after primary ChEVAS.

Limb/chimney occlusions. Thromboembolic complications affected both the Nellix stent-grafts (3 limb occlusions in the group of primary ChEVAS (1 of which occurred in the presence of migration) and 1 in the group of secondary ChEVAS), as well as the chimney stent-grafts (3 and 1 in the group of primary and secondary ChEVAS, respectively.

An overview of clinical outcomes is displayed in Table III. Aside from the event endoleak type Ia, (primary ChEVAS 43% vs. secondary ChEVAS 8%, $P = 0.0374$), the occurrence of complications did not significantly differ between the 2 groups. In addition, the logistic regression analysis revealed that no specific anatomical parameter (e.g. thrombus ratio, proximal neck length, aneurysm diameter, etc.) or procedural parameter (e.g. sealing zone, number of target vessels) had a significant impact upon the event "endoleak and/or migration". Figure 4 shows the temporal distribution of

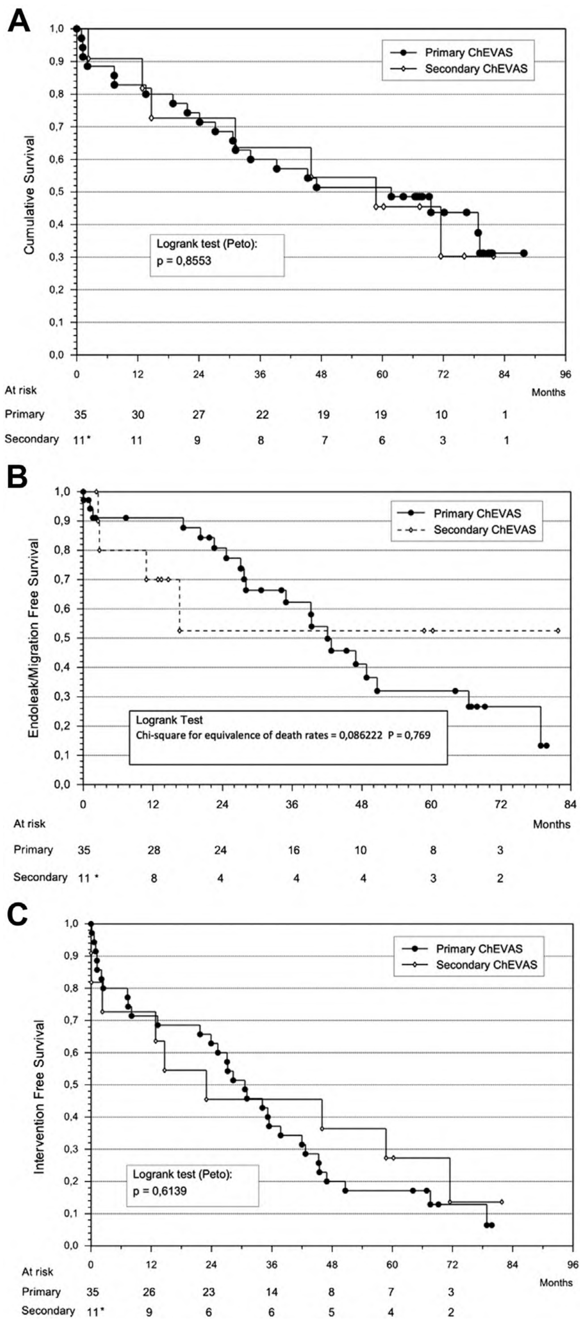

Fig. 2. Kaplan-Meier curves for **(A)** cumulative survival, **(B)** endoleak and/or migration free survival, and **(C)** reintervention-free survival after primary and secondary Chimney Endovascular Aneurysm Sealing (ChEVAS). * One out of 12 patients in the group of secondary ChEVAS was lost to follow-up.

the 23 aneurysm-related events (endoleak and/or migration and/or aneurysm rupture) that occurred (median 27 months, range 0−79) within the groups of primary and secondary ChEVAS.

Secondary interventions. A secondary intervention was carried out in a total of 21 (45%) patients: 18 (51%) patients with primary and 3 (25%) with secondary ChEVAS, respectively. In the group of primary ChEVAS, the most frequent reintervention was conversion to open surgery, which affected 9 patients: While 4 were emergently converted in the setting of aneurysm rupture and 5 electively due to endoleak and migration, all 9 of them presented with aneurysm growth. Eight patients received a bifurcated graft (3 of which were combined with renovisceral bypasses) and 1 patient received a tube graft with complete renovisceral debranching. In total, 1 celiac trunk, four mesenteric and 4 renal bypasses were carried out, respectively. The conversion was survived by 6/9 patients, procedural details have been described in a previous publication.[24]

Another 3 patients received a distal Nellix-in-Nellix-Application (NINA) in the setting of endoleak type Ib (in 1 case with associated aneurysm rupture), while 1 patient was treated with coil-embolization for an endoleak type Ia. Apart from abovementioned procedures, the following reinterventions were performed: 1 surgical revision of the infected axillary access site with vein patch plasty, 1 transfemoral embolectomy, and 1 crossover bypass (both for the treatment of endograft limb occlusions). Two endovascular chimney reinterventions were performed for renal stenosis or occlusion, one of which later resulted in a proximal NINA plus chimney-in-chimney procedure.

In the group of secondary ChEVAS, two elective conversions to open surgery were carried out: 1 patient was converted due to migration with subsequent limb occlusion (which had previously been treated with endovascular revascularization). Another patient was converted due aneurysm growth in the setting of an endoleak type V (the same patient had previously received an endovascular chimney reinterventions for renal stenosis/occlusion). Both patients were treated with a bifurcated graft (1 in combination with a renal bypass) and both survived the explantation.

In addition, 1 nephrectomy was performed due to active bleeding after a secondary ChEVAS procedure.

An overview of all secondary interventions is shown in Table IV, while Figure 2 C displays the Kaplan-Meier curve for cumulative freedom from reintervention. Table V displays an overview of patients presenting with secondary a rupture after primary ChEVAS.

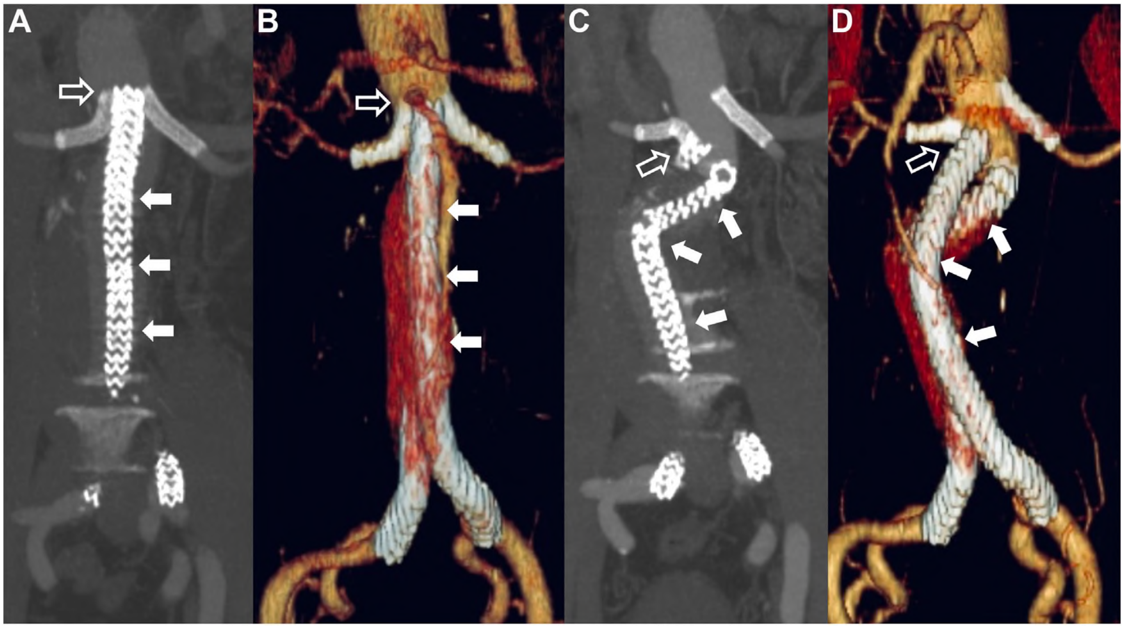

Fig. 3. Initial postoperative CT scan **(A)** and three-dimensional CT reconstruction **(B)** after primary Chimney Endovascular Aneurysm Sealing (ChEVAS). White arrows demonstrating the straight configuration of the main Nellix stent-grafts, black arrow pointing to the well aligned proximal sealing zone with 2 renal chimney grafts. CT scan **(C)** and three-dimensional CT reconstruction **(D)** approximately 3 years (33 months) later. White arrows demonstrating the massively kinked, migrated Nellix stent-grafts, black arrow pointing to the completely lost proximal sealing zone with free floating renal chimney grafts.

DISCUSSION

To the authors' best knowledge this is the first study to report 5 year results of a cohort of 47 consecutive patients treated with primary ChEVAS for complex AAA or secondary ChEVAS after failed EVAR EVAR/EVAS. Overall, the longer-term results after ChEVAS are quite sobering: Both groups show high rates of complications and subsequent secondary interventions.

This is particularly disappointing, as these cases initially presented a high technical success rate (97% and 92% for primary and secondary ChEVAS, respectively) in a morphologically challenging group of patients, including redo cases of previously failed EVAR/EVAS. In hindsight, these seductive early results should have been taken with caution, as even standard aneurysm sealing itself still resembled a new technique at the time and other well-known endovascular solutions would have been available.[24] Using a new technology outside of its instructions for use (which was the case with every single ChEVAS procedure), poses a great risk as demonstrated by the disillusioning results of the present study. In accordance with Harrison et al. we hence support the approach that all novel devices should be regarded as ''experimental'' until long-term data encourage the implementation into common practice.[25]

It remains challenging to understand the mechanisms leading to failure after ChEVAS, as there are only few reports regarding this technique.[16–18,21] Interestingly, as evident in Table III, the development of complications seems to be a multifactorial process: the majority of patients affected by an endoleak (23/47) also suffered from migration (16/23) and/or aneurysm growth (18/23). These findings are in line with previous studies reporting a combination of endoleak, migration and aneurysm growth after (ChEVAS.[25–27] What remains unclear, however, is which element of the composite event comes first: Does the loss of proximal sealing lead to migration and aneurysm growth, or is it rather the migration itself resulting in disruption of the proximal landing zone and subsequent endoleak and/or aneurysm growth.[24] One argument in favor of the latter theory is the fact that the Nellix stent-graft does not use radial force to achieve fixation within a so called ''healthy'' aortic neck, but rather builds its foundation on the aneurysm sac itself by lining it with polymer filled endobags. As such it has no options to adapt to anatomical or structural changes of the (thrombus filled) aneurysm, which might explain why ChEVAS shows no superior results over standard EVAS. After all,

Table III. Overview of clinical outcomes after primary and secondary Chimney Endovascular Sealing (ChEVAS)

Clinical outcomes	Total 47 (100)	Primary ChEVAS 35 (100)	Secondary ChEVAS 12 (100)	*P* value
Technical success	45 (96)	34 (97)	11 (92)	0.4174
All-cause mortality	28 (60)	21 (60)	7 (58)	>0.9999
Intraoperative death	0	0 (0)	0 (0)	n.a.
30-day-mortality	2 (4)	1 (3)	1 (8)	0.2513
Aneurysm-related mortality	11 (23)	10 (29)	1 (8)	0.244
Cancer-related mortality	6 (13)	4 (11)	2 (17)	0.6372
Any endoleak	23 (49)	20 (57)	3 (25)	0.193
Endoleak type Ia	16 (34)	15 (43)	1 (8)	0.0374
Endoleak type Ib	4 (9)	4 (11)	0 (0)	0.5597
Endoleak type II	1 (2)[a]	0 (0)	1 (8)[a]	0.2553
Endoleak type V	3 (6)	1 (6)	2 (17)	0.156
Migration	16 (34)	14 (40)	2 (17)	0.141
Aneurysm growth	18 (38)	15 (40)	2 (17)	0.141
Aneurysm rupture	7 (15)	7 (20)	0 (0)	0.1665
Endograft limb thrombosis	4 (9)	3 (9)	1 (8)	0.9797
Chimney graft thrombosis	4 (6)	3 (9)	1 (8)	0.9797
Total # of patients affected by complications	27	22 (63)	5 (42)	0.2001

[a]Since the endoleak type II did not affect the ChEVAS procedure, but rather the previously implanted EVAR device, it was not counted as ChEVAS associated.

both EVAS and ChEVAS use the same sort of foundation (or mode of fixation), hence it does not come as much of a surprise that building another story on top does not make the architecture of EVAS more stable.

Regardless, the amount of thrombus within the aneurysm (i.e. the thrombus ratio) was not identified to be a predictor for the development of an aneurysm-related event (endoleak and/or migration and/or aneurysm rupture) in the logistic regression analysis. Hence, having a ''good'' thrombus ratio <1.4 did not protect patients from developing 1 of the abovementioned complications, a finding that is in line with previous publications.[24,26,28]

Interestingly, aside from the event endoleak type Ia (primary ChEVAS 43% vs. secondary ChEVAS 8%, $P = 0.0374$), the occurrence of complications did not significantly differ between the 2 groups. While the small sample size might explain the lack of significance here, the 2 migrations detected in the group of secondary ChEVAS were both found in cases that had previously received an EVAS procedure. Whether this supports the theory that a previously implanted EVAR stent-graft might represent a more solid foundation for EVAS remains unknown.

Of note was the temporal distribution of the occurrence of complications displayed in Figure 4: Just about a quarter (6/23) of aneurysm-related events such as endoleak and/or migration and/or aneurysm rupture occurred within the first year after the index procedure. Close to 60% (13/23) of abovementioned complications took place past the first 2 years after the ChEVAS procedure. This once again highlights the need of prolonged rigorous follow-up after ChEVAS and is in accordance with many studies that assessed the durability after ''normal'' EVAS, the most recent being a report by Ferrero et al. describing a Nellix Stent rupture 7 (!) years after the initial implantation.[24,28–30]

Hence, the very early results of the chEVAS 1 trial just recently published by Prakash et al. (reporting a 100% technical success rate after primary ChEVAS in 4 patients, with a short follow-up of just 6 weeks for 2 patients and only 6 months for the remaining 2) are not surprising.[20] They very much resemble our own early experience with this procedure: Satisfying early angiograms in complex aortic repair, all established with an off the shelf procedure. However, as we have learned the hard way, those results are unlikely to withstand the test of time.

Speaking of follow-up, it is important to discuss the alarmingly high mortality rates in the present study: The freedom from ACM was 85% at 1 year, 74% at 2 years and 50% at 5 years, while the freedom from ARM was 93% at 1 year, 88% at 2 years and 73% at 5 years, respectively.

These findings are astonishingly in line with previously published data of Chimney-EVAR (ChEVAR), with the PERformance of the chImney

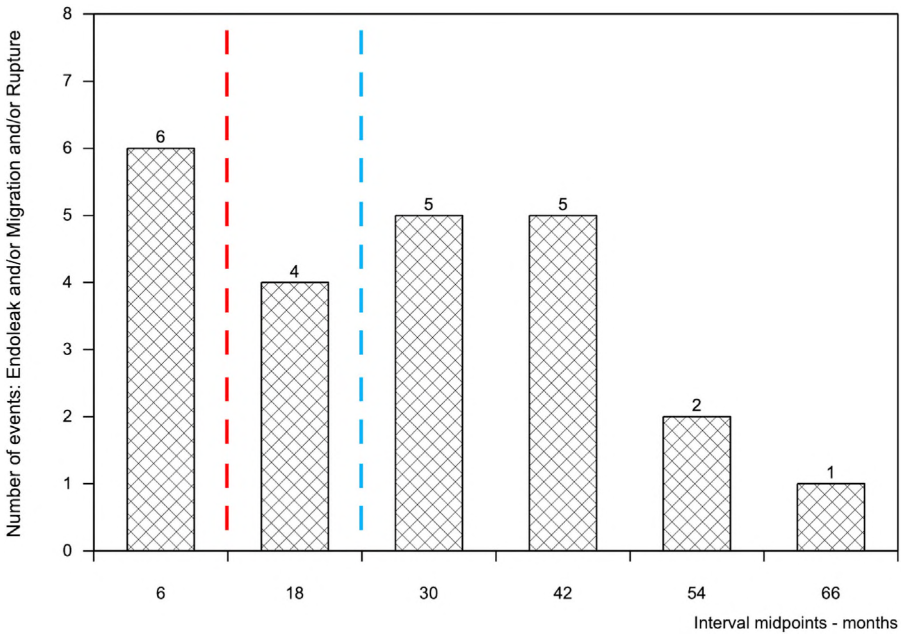

Fig. 4. Temporal distribution of the 23 aneurysm-related events (endoleak and/or migration and/or aneurysm rupture) that occurred (median 27 months, range 0–79) within the groups of primary and secondary ChEVAS. The red dashed line marks the 1-year interval, while the blue dashed line marks the 2-year interval. Accordingly, 26% (6/23) aneurysm-related events happened within the first year and a total of 43% (10/23) within the first 2 years. Hence, 57% (13/23) aneurysm-related events occurred beyond 2 years of follow-up.

technique for the treatment of Complex aortic pathoLogiES registry representing the largest data set with an estimated patient survival of 87.6%, 74.4%, and 66.1% at 1, 3, and 5 years, respectively.[31] Other ChEVAR studies report even lower survival rates, ranging from a 1-year survival rate of 61% (with an aneurysm-related death rate of 22%) to a 5-year survival of 53%.[32,33] Accordingly, two multicenter studies found that ChEVAR was associated with more complications and worse outcomes as compared to fenestrated EVAR, one possible explanation being that candidates for ChEVAR are usually the ones excluded from fenestrated EVAR due to either unfavorable anatomy or the impossibility to await the production of a custom-made device.[34,35] Interestingly (and also in line with our findings), the number of targeted vessels was not associated with the occurrence of major or minor complications.[36]

When it comes to a comparison to previously published data after ChEVAS, the few existing studies are limited both in size and follow-up. However, while early ChEVAS results were promising, Dzieciuchowicz et al. already reported a cumulative ACM of 15, 21, and 36% at 12, 24, and 36 months and a cumulative ARM of 8, 11, and 27% at 12, 24, and 36 months, respectively.[16–18,21] These data reflect our own findings and further discourage the use of the chimney technique in combination with EVAS.

Regardless of the ChEVAS procedures performed, it must be taken into consideration that 1 possible reason for the relatively high ACM in the present study might be the circumstance that close to 3-quarters (35/47) of the patients were ranked American Society of Anesthesiologists class III or IV, representing a highly diseased patient cohort.

Regarding the management of complications, a secondary intervention was carried out in a total of 21 (45%) patients in the present study. The most frequent reintervention was conversion to open surgery, which was performed in a total of 11 patients, 10 of whom presented with aneurysm growth. Details of the explantations have previously been published, but the fact that the majority (8/11) of patients survived the explantation, raises the question why they had not received an open aortic repair in the first place.[24] Taking our own experience of managing EVAS complications (with and without chimney grafts) into account, we strongly believe that conversion to open surgery is the best choice for patients fit enough for explantation, which is in accordance with

Table IV. Secondary interventions after primary and secondary Chimney Endovascular Sealing (ChEVAS)

Secondary interventions	Total 47 (100)	Primary ChEVAS 35 (100)	Secondary ChEVAS 12 (100)	*P* value
Open Conversion/Explantation	11 (23)	9 (26)	2 (17)	0.523
Distal Nellix-in-Nellix-Application (NINA)	3 (6)	3 (9)	0 (0)	0.2946
Proximal NINA plus chimney-in-chimney	1 (2)	1 (3)	0 (0)	0.5539
Proximal coil embolization	1 (2)	1 (3)	0 (0)	0.5539
Endovascular chimney recanalization	3 (6)	2 (6)[a]	1 (8)	0.7488
Nephrectomy due to active bleeding	1 (2)	0 (0)	1 (0)	0.0843
Surgical axillary access site revision	1 (2)	1 (3)	0 (0)	0.5539
Crossover bypass	1 (2)	1 (3)	0 (0)	0.5539
Open transfemoral endograft limb embolectomy	1 (2)	1 (3)	0 (0)	0.5539
Endovascular recanalization of endograft limb	1 (2)	0 (0)	1 (8)[b]	0.0843
Total # of patients with secondary intervention	21 (45)	18 (51)	3 (25)	0.112

[a]Of the 2 patients who received an endovascular chimney recanalization, one was later converted to open surgery, while the other later received a proximal NINA plus chimney-in-chimney procedure.
[b]The patient was later converted to open surgery.

Table V. Overview of patients presenting with a secondary rupture after primary ChEVAS ($n = 7$)

Clinical presentation	Total n = 7		
Endoleak Ia	6		
Endoleak Ib	1		
Migration	5		
Aneurysm growth	6		
Outcome	Total n = 7	Survived	Died
Conversion to open surgery	4	3	1
Distal Nellix-in-Nellix-Application (NINA)	1	1	0
Palliative care	2	0	2

There were no secondary ruptures after secondary ChEVAS.

Stenson et al. describing how EVAS failures are dealt with at their vascular unit.[24,37]

When open surgery is no option due to patient fragility, dealing with ChEVAS complications becomes more challenging, as the design of the EVAS system limits the endovascular options usually available. One possible therapy in the setting of endoleak is coil embolization, which was performed for 1 case of a small endoleak type Ia among the group of primary ChEVAS. However, this technique with either coil of liquid embolization is only supported by sparse data and should only be used in minor type I endoleaks.[38–41]

A more established solution is the NINA, which was used in 3 cases of endoleak type Ib, as well as in combination with chimney-in-chimney in 1 case of endoleak type Ia. While this procedure is technically viable and has been described in various reports, the largest being a multicenter study by Zoethout et al., it should be taken into consideration, that it does not treat the underlying problem, namely a failing, often migrated EVAS graft.[18,24,42–44] Also, NINA requires an ethics approval and special order by Endologix and is hence not rapidly available.[24]

One last option for the treatment of type Ia endoleaks after ChEVAS might be multibranched devices with a narrow distal ending, that allow landing in 1 of the 10 mm wide Nellix grafts, with 1 extra branch for the remaining Nellix limb, or with subsequent plugging the other Nellix limb and femoral crossover bypass. Experience with this technique is once again very limited and as such resembles a bailout solution.[42,45]

Limitations

While reporting the longest follow-up post ChEVAS to date, the present study still has certain shortcomings. First, it only represents a single-center experience with retrospective data analysis of a cohort of 47 consecutive patients. In addition, it contains a learning curve with a new stent-graft system, even more so as it was used with chimney grafts (after previously performing 21 standard EVAS procedures). As such, only limited conclusions can be drawn regarding on why and how the complications occurred. Consequently, further data and prospective collection would be needed to gain a better understanding of the long-term performance of ChEVAS. However, given the results of the current study, we do not advise use of this procedure, even in an experimental setting, unless the EVAS system itself, including the polymer, is enhanced.

CONCLUSION

While initially delivering a high technical success rate, ChEVAS fails to provide acceptable longer-term results both in primary and secondary ChEVAS, resulting in high rates of complications, secondary interventions and open conversions. The logistic regression analysis revealed that no specific anatomical parameter (e.g. thrombus ratio, proximal neck length, aneurysm diameter, etc.) or procedural parameter (e.g. sealing zone, number of target vessels) had a significant impact upon the event ‘‘endoleak and/or migration’’, making an understanding of said complications difficult. As close to 60% of aneurysm-related complications took place past the first 2 years after the index procedure, it is important to highlight the need of prolonged rigorous follow-up after ChEVAS.

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