Multicenter Mid-Term Outcomes of the Chimney Technique in the Elective Treatment of Degenerative Pararenal Aortic Aneurysms

Georgios A. Pitoulias, MD, PhD[1,2*], Stefano Fazzini, MD, PhD[3*], Konstantinos P. Donas, MD, PhD[2], Salvatore T. Scali, MD, PhD[4], Mario D'Oria, MD, PhD[5], Giovanni Torsello, MD, PhD[6], Frank J. Veith, MD, PhD[7], and Stefan B. Puchner, MD, PhD[8]

Abstract

Purpose: Chimney endovascular abdominal aortic aneurysm repair (CHEVAR) has predominantly been described as an alternative technique for the management of urgent presentations of degenerative pararenal aortic aneurysms (dPAAs). However, the role of CHEVAR in the treatment of asymptomatic patients remains unknown. The aim of current multinational study was to evaluate the outcomes of elective CHEVAR of dPAAs. **Material and Methods:** Retrospective analysis of 267 consecutive dPAA patients treated with elective CHEVAR at 13 European and US centers from 2008 to 2014. Primary endpoints were 30 days and out of hospital CHEVAR-related mortality. Secondary endpoints included persistent type Ia endoleak or endotension, angiographically confirmed occlusion and/or high-grade chimney graft (CG) or involved splanchnic vessel stenosis identified at index procedure and/or during follow-up, as well as CHEVAR-related re-intervention. **Results:** Mean follow-up time was 25.5±13.3 months. The 442 visceral vessels were involved and mean number of CGs per patient was 1.63±0.7. 436 targeted vessels were successfully cannulated. The aortic graft intentionally covered 6 renal arteries and immediate technical success was 98.6%. The 30 days mortality was 1.9% (n=5), while the in-hospital complication rate was 10.1% (n=27) including 3 strokes, 1 permanent dialysis, and 1 intestinal ischemia. No 30 day type Ia endoleaks were detected and 3.2% of CGs (n=14, including the intentionally covered) had evidence of occlusion and/or stenosis. The overall CHEVAR-related mortality was 2.2% (n=6). Freedom from primary and secondary type Ia endoleak/endotension rates at 3 years was 93.0% and 98.0%, respectively. Primary and secondary CG patency was 87.0% and 89.0%. Primary and secondary endovascular freedom from any endpoint at 3 years was 81.0% and 94.0% respectively. **Conclusion:** Elective use of CHEVAR in the management of dPAAs seems to be durable. These results are comparable to published outcomes with other total endovascular strategies, which justifies an expanded role for CHEVAR in the treatment of asymptomatic patients presenting with dPAAs.

Keywords

pararenal, chimney, aortic, aneurysm, degenerative, elective

Introduction

Over the past decade, the role of chimney endovascular abdominal aortic aneurysm repair (CHEVAR) in the management of complex abdominal aortic aneurysms (AAA) and other pararenal aortic pathologies has rapidly evolved.[1–3] Due to increasing adoption and maturation of the peer-reviewed evidence, CHEVAR has been increasingly reported to manage a variety of clinical scenarios. Indeed, this technique was endorsed and is now included in the most recent Society for Vascular Surgery and European society for Vascular Surgery AAA Practice Guidelines.[4,5] Notably, CHEVAR has predominantly been justified as "an alternative in the emergency setting or when fenestrated stent grafts are not indicated or available or as a bailout, ideally restricted to ≤2 chimneys."[5]

To date, a significant limitation of the reported CHEVAR experience is the inclusion of heterogeneous patient populations. Specifically, many series include symptomatic and/or ruptured presentations, pararenal/suprarenal aneurysm morphologies, as well as post-surgical pseudoaneurysm and/or type Ia endoleak remediations.[3,6] Consequently, despite the generally favorable results reported thus far, the role of

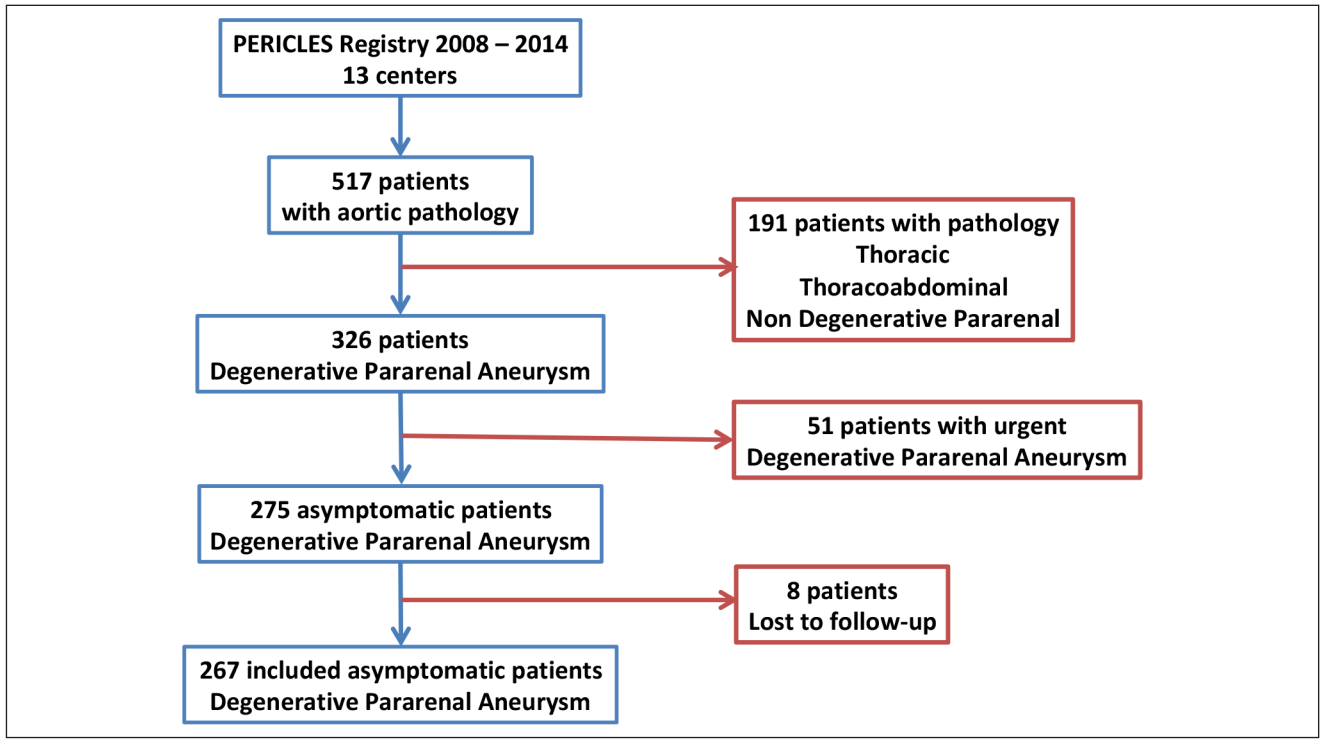

Figure 1. Flowchart showing the identification and inclusion of 267 patients from PERICLES registry.

CHEVAR in the management of asymptomatic degenerative pararenal AAA (dPAA) remains poorly understood.

Therefore, the purpose of the current study was to analyze and report the early and mid-term outcomes of elective CHEVAR of asymptomatic dPAAs using a multi-national dataset.

Materials and Methods

The multicenter **PER**formance of the ch**I**mney technique for the treatment of **C**omplex aortic patho**L**ogi**ES** (PERICLES) registry was analyzed.[7] The registry complied with the principles of the Declaration of Helsinki. A total of 13 centers from Europe (n=9) and the USA (n=4) constitute the multi-national collaborative study group. The respective institutional review boards and local ethics committees of the individual participating sites approved the data acquisition and collection. A retrospective chart and imaging review, using 3D centerline imaging analysis,[8] was performed at each site and abstracted data elements were entered in a de-identified central data repository for further analysis.

From 2008 to 2014, a total of 517, high-risk for open repair, patients with 8 different types of aortic pathology were treated using CHEVAR in the participating centers, while a dPAA was present in 326 (63.1%) patients. After exclusion of the symptomatic and/or ruptured presentations, there were 275 (53.2%) asymptomatic patients with dPAA. Eight subjects were lost to follow-up leaving a total of 267 (51.6%) being available for analysis. Figure 1 shows

[1]Division of Vascular Surgery, 2nd Department of Surgery, School of Medicine, Aristotle University of Thessaloniki, G. Gennimatas Hospital, Thessaloniki, Greece
[2]Department of Vascular Surgery, Research Vascular Centre, Asklepios Clinic Langen, University of Frankfurt, Langen, Germany
[3]Department of Vascular Surgery, San Filippo Neri Hospital, Rome, Italy
[4]Division of Vascular Surgery and Endovascular Therapy, University of Florida College of Medicine, Gainesville, FL, USA
[5]Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Cattinara ASUITs, Trieste, Italy
[6]Department of Vascular Surgery, St. Franziskus Hospital Münster, Münster, Germany
[7]New York University and Cleveland Clinic Foundation, New York, NY, USA
[8]Department of Radiology and Biomedical Imaging and Image-Guided Therapy, Medical University of Vienna, Vienna, Austria

*These authors contributed equally on this manuscript and they share the first authorship place.

Corresponding Author:
Georgios A. Pitoulias, Division of Vascular Surgery, 2nd Department of Surgery, School of Medicine, Aristotle University of Thessaloniki, G. Gennimatas Hospital, 41 Ethnikis Aminis str, Thessaloniki, 54635, Greece.
Emails: pitoulias@yahoo.com; gpitouli@auth.gr

Table 1. Patients' Inclusion in Study of Elective CHEVAR.

PERICLES patients	n (%)
Total	517 (100)
dPAA	326 (63.1)
Asymptomatic dPAA	275 (53.2)
Lost to follow-up	8 (2.9)
Relocation abroad	3 (1.1)
Denied follow-up/pure clinical condition	2 (0.7)
Unknown reason	3 (1.1)
Included	267 (97.1)
Short infrarenal proximal aortic neck (median/IQR length 4.5/2.5 mm)	8 (3.0)
Juxtarenal	165 (61.8)
Suprarenal	94 (35.2)

Categorical data are given as the counts (percentage).
Abbreviations: dPAA, degenerative pararenal aortic aneurysms; IQR, interquartile range; PERICLES, **PER**formance of the ch**I**mney technique for the treatment of **C**omplex aortic patho**L**ogi**ES**.

the flowchart of patients' inclusion and Table 1 provides additional detail about the patients included for analysis.

Definitions and Endpoints

Details regarding the indications for the procedure, technical conduct and definitions of patient co-morbidities were previously published.[2,3,7] dPAAs were defined as aneurysms, degenerative in etiology, that had no sufficient length of normal aorta between the upper extent of the aneurysm and the renal arteries to allow a conventional EVAR or necessitating suprarenal aortic clamping for open repair. They were further classified into 3 types; short infrarenal neck, juxtarenal, and suprarenal dPAAs. Definition of short infrarenal neck included aneurysms with proximal aortic length $\leq$8 mm. Juxtarenal dPAAs included all infrarenal aortic aneurysms adjacent to or including the lower margin of renal artery origin(s), whereas dPAAs extended to the suprarenal aortic segment with involvement of renal artery(ies) but sparing the orifice of the superior mesenteric artery were classified as suprarenal dPAAs (Table 1).

The primary end-points of the study were all cause 30 day mortality, as well as CHEVAR-related mortality during follow-up. Secondary end-points included detection of proximal sealing zone failure in terms of persistent type Ia endoleak or endotension, chimney failure in terms of chimney graft (CG) or involved splanchnic vessel occlusion or high-grade ($>$70%) stenosis and any CHEVAR-related re-intervention during follow-up.

Persistent type Ia endoleak was defined by presence on the 1 month postoperative computed tomographic arteriogram (CTA) and/or on any subsequent follow-up imaging after that time period and was considered as proximal sealing zone failure. Accordingly, intraoperative type Ia endoleak that resolved by the first postoperative CTA was not considered for this analysis. Additionally, cases with continued sac expansion during follow-up with an indeterminate endoleak from presumed endotension were also adjudicated to have a potential type Ia endoleak and were considered as proximal sealing zone failures. The rationale for this consideration was our attempt to eliminate the possibility of concealing misdiagnosed Ia endoleaks cases as endotensions.

Loss of any branch vessel (planned or unplanned), as well as CG patency were analyzed. CG failure was verified by detection of a high-grade ($>$70%) stenosis and/or occlusion with catheter-based arteriography (intraoperative or at any time postoperatively) or CTA during follow-up. Notably, intentional coverage of a splanchnic vessel ostium by the aortic graft at time of the index procedure was reported separately from CG patency failure but a full accounting of these events is provided for full transparency about the number of renal-visceral vessels that were impacted by the experience.

Re-intervention events (either open or endovascular) after the index CHEVAR procedure were categorized as being CHEVAR-related or non-related. The term CHEVAR-related describes any secondary procedure performed to address any index procedure related complication, proximal sealing zone failure, CG failure, and/or any remedial procedures of the main body aortic-stent within the intended treatment zone. Non-CHEVAR related re-intervention included procedures performed for treatment of other types of endoleak (ie, type II/III) or for treatment of iliac and/or peripheral vasculature, and/or aortic pathology outside the intended treatment zone.

Clinical success was defined by absence of primary and secondary endpoint events. Secondary clinical success achieved in all patients underwent a successful endovascular CHEVAR-related re-intervention. Outcomes of secondary open CHEVAR-related re-interventions were considered as failures of the total endovascular solution and were not counted in secondary clinical success. Finally, as immediate technical success of index procedure was defined the completion of CHEVAR with patency of main graft and all involved splanchnic vessels. The anticipated detection of gutter's associated type Ia endoleak on final completion angiogram was not count in immediate technical success and was further assessed at first month follow-up.

Statistical Analysis

Categorical variables are presented as counts and percentages. Continuous variables are presented as mean $\pm$ standard deviation if the data were normally distributed, or as median with interquartile range (IQR) if the data were skewed (as verified by Shapiro–Wilk test). Continuous and categorical variables were compared using the non-parametric Wilcoxon signed rank test and Fisher's exact chi

Table 2. Demographics and Comorbidities of 267 dPAA Patients Treated by Elective CHEVAR.

Demographics	Mean	SD
Age (y)	75.2	7.4
	n	%
Gender Male/Female	219/48	82.0/18.0
ASA Classification III/IV	172/95	64.4/35.6
Co-morbidities[a]	**n**	%
Hypertension (Blood pressure 140–159/90–99 mmHg)	236	88.4
Dyslipidemia (Cholesterol>200–240 mg/dL or triglycerides>200 mg/dL)	177	66.3
Coronary artery disease	139	52.1
Congestive heart failure (Ejection fraction <40%)	108	40.4
Chronic obstructive pulmonary disease (FEV_1 <80%)	115	43.1
Chronic renal insufficiency (GFR≤60 mL/min)	113	42.3
GFR≤60 mL/min	65	24.3
GFR≤60 mL/min	38	14.2
GFR<30 mL/min (Dialysis)	10 (5)	3.7 (1.9)
Diabetes mellitus (HbA1c>6.5%)	44	16.9
Peripheral artery disease (ABI<0.9)	61	22.8
Smoking (current or cessation <6 mo)	58	21.7
Oral Medication		
Aspirin	180	67.4
Clopidogrel	43	16.1
Oral anticoagulant	39	14.6
B-Blocker	130	48.7
Statin	168	62.9

Continuous data with normal distribution are presented as the mean ± standard deviation; Categorical variables are presented as the counts (percentage).
Abbreviations: ASA, American Society of Anestesiologists physical status classification system; FEV1, Forced Expiratory Volume during the first second; GFR, Glomerular Filtration Rate; SD, standard deviation.
[a]Definition of co-morbidities was based in medical history of relevant diagnosis and/or previous medical or surgical treatment and/or in the above physical or laboratory examination findings.

square test as appropriate. Estimation of freedom from primary and secondary endpoints at 3 years postoperatively was determined by Kaplan–Meier life table analysis. All statistical tests were 2-sided, and a p value <0.05 was considered significant. Data were analyzed using SPSS 25.0. (IBM).

Results

Study Cohort

A total of 267 patients were identified with mean age 75.2±7.4 years and 82.0% (n=219) were male. Additional details regarding the demographics and comorbidities are presented in Table 2. Similarly, a summary of the perioperative aneurysm related details, as well as intraoperative technical details are highlighted in Table 3.

The total number of potentially involved visceral/renal branch vessels was 442. The 6 vessels (3 right and 3 left renal arteries) were intentionally covered by the aortic endograft and the remaining 436 target vessels were all successfully cannulated. Immediate technical success was 98.6%. Nine of the 436 vessels underwent unplanned CGs during the index procedures. The mean number of CGs deployed per patient was 1.63±0.7. Self-expanding and balloon expandable CGs were implanted in 236 (54.1%) and 190 (43.6%) branch vessels, respectively. In the remaining 10 (2.3%) splanchnic vessels, a bare metal, balloon expandable chimney stent was deployed. Internal lining of the chimney stent with a bare metal, self-expanding stent occurred in 79 (17.9%) vessels. Additional details about the individually targeted vessels and implanted CGs are tabulated in Table 4.

Overall Primary Endpoint Outcomes

There were 39 postoperative complications recorded in 27 (10.1%) patients and the 30 day mortality rate was 1.9% (n=5). Four patients died from cardiorespiratory failure (1 of them experienced also a stroke) and 1 died from intestinal ischemia due to SMA's CG occlusion. CHEVAR procedure related mortality at any time during follow-up was

Table 3. Anatomical and Operative Data of 267 dPAAs Treated by Elective CHEVAR Procedure.

Anatomical	Median	IQR
Aneurysm's maximum diameter (mm)	61.0	15.0
Proximal aortic neck diameter (mm)	26.0	6.6
Proximal aortic neck length (mm)	0.0	0.5
Proximal aortic neck length increase (mm)	20.0	8.5
New CHEVAR proximal aortic neck length (mm)	20.0	8.0
Suprarenal aortic neck angulation (°)	14.5	25.0
	n	%
Proximal aortic neck's circumferential thrombus >50%	34	12.7
Proximal aortic neck's circumferential calcification >50%	39	14.6
Operative	Median	IQR
Total duration of procedure (min)	200	82.5
Fluoroscopy time (min)	62	46.8
Contrast medium (mL)	150	89
Graft configuration	n	%
Bifurcated	246	92.1
Aortic tube/Aortouniliac	17/4	6.4/1.5
Brand of endograft	n	%
Endurant	116	43.4
Zenith	66	24.7
Excluder	48	18.0
Other graft with suprarenal fixation	37	13.9
Adjunctive primary procedure	n	%
Additional proximal aortic cuff	19	7.1
Concomitant thoracic endografting	5	1.9
Crossover femoro-femoral bypass	2	0.7
Iliofemoral conduit	1	0.4
Axillary conduit	7	2.6
Iliac stent angioplasty	16	6.0
Open iliac or femoral or peripheral procedure	5	1.9

Categorical variables are given as the counts (percentage). Continuous variables with skewed distribution are presented as median and interquartile range.
Abbreviations: CHEVAR, chimney endovascular abdominal aortic aneurysm; IQR, interquartile range.

2.2% (n=6; 5 occurred within 30 days postoperatively and 1 was attributed to CHEVAR-related complication after 30 days), while the overall mortality was 21.0% (n=56). Table 5 summarizes the morbidity and mortality events, while Figure 2 demonstrates the Kaplan–Meier survival curve estimates at 3 years. The relevant estimated overall survival was 75.0±0.2% while freedom from CHEVAR-related mortality was 98.0±0.1%.

Early Secondary Endpoint Outcomes

Proximal Sealing Zone Failure. During the index procedure, a total of 15 (5.6%) adjunctive maneuvers were performed prior to completion angiogram and 19 (7.1%) afterward. More specifically prior to completion angiogram, a single proximal aortic cuff extension was deployed in 6 patients and in the remaining 9 cases the aortic cuff extension was combined with additional (unplanned) CG placement. On initial completion angiogram a total of 21 (7.9%) patients were identified with a potential proximal sealing zone failure. Twenty were Ia endoleaks while 1 case was due to aortic endograft caudal migration/misplacement without visible endoleak. Corrective treatment consisted of kissing-balloon dilatations of the aortic stent graft and CGs in 15 and additional single proximal aortic cuff extension in 4 patients. Subsequently, completion angiograms for all 19

Table 4. Operative Data of 442 Chimney Graft in 267 Elective CHEVAR Procedures.

Targeted vessel and CG	n	%
Right renal (md 6 mm)	177	40.0
Balloon expandable	71	16.1
Self-expanding	99	22.3
Bare metal stent	4	0.9
Intentionally covered	3	0.7
Left renal (md 6 mm)	198	44.8
Balloon expandable	91	20.6
Self-expanding	98	22.2
Bare metal stent	6	1.4
Intentionally covered	3	0.7
Large accessory/ectopic renal (md 5.5 mm)	2	0.5
Balloon/self expanding	1/1	0.2/0.2
Superior mesenteric artery/celiac trunk (md 7 mm/7 mm)	54/11	12.2/2.5
Balloon expandable	26/1	5.9/0.2
Self-expanding	28/10	6.3/2.3
Lining with bare metal stent	79	17.9
Right renal	27	6.1
Left renal	35	7.9
Superior mesenteric	1	0.2
Both renals	4 (8 vessels)	1.8
Both renals + Superior mesenteric + Celiac trunk	2 (8 vessels)	1.8
Total CGs	436	100
Balloon expandable	190	43.6
Self-expanding	236	54.1
Bare metal stent	10	2.3
Mean ± SD number of CGs per patient	1.63±0.7	

Categorical variables are given as the counts (percentage). Continuous variables with normal distribution are presented as the mean ± standard deviation.
Abbreviation: CG, chimney grafts; md, median diameter of used CG.

patients demonstrated resolution of type Ia endoleak prior to leaving the operating room. Finally, 2 (0.7%) type Ia endoleaks were considered "gutter related" and did not undergo intraoperative remediation. For these 2 patients, at first month follow-up, the postoperative CTA demonstrated thrombosis of the type Ia endoleak and no evidence of new endoleak. Notably, a type II endoleak was identified in 29 (10.9%) patients at some point during follow-up.

Chimney Failure. In addition to the 6 vessels (3-right renal, 3-left renal) that were intentionally covered by the aortic endograft, a single renal artery underwent planned intraoperative CG placement and was noted on completion arteriogram to be occluded. The total intraoperative visceral vessel occlusion rate was 1.6% (n=7) and the CHEVAR-related intraoperative chimney occlusion rate was 0.2% (1 of 436 CGs). At 30 day follow-up, 7 (1.6%) additional CGs (6 renal arteries and 1 SMA) were documented to be occluded in 6 (2.2%) patients. Overall, during the initial 30 day follow-up period, 14 (3.2%) of the involved visceral vessels were occluded in 13 (4.9%) patients. The 2 patients (0.7%) developed new onset acute renal failure, 5 (1.9%) experienced only flank pain and 5 (1.9%) remained completely asymptomatic. The patient with SMA occlusion developed acute intestinal ischemia and died. In 3 (1.1%) patients, a successful endovascular re-intervention was performed to revascularize the thrombosed renal CG, which remained patent during follow up. Additional information regarding the intraoperative and 30 day results are reported in Table 6.

Mid-Term Secondary Endpoint Outcomes. The mean radiographic and clinical follow-up time was 21.8±13.3 and 25.5±13.3 months, respectively. The median–IQR preoperative maximum AAA diameter decreased significantly during follow-up: 61.0–15.0 mm versus 56.0–17.0 mm ($p<0.001$, Table 7).

Proximal Sealing Zone Failure. During follow-up, a total of 19 (7.1%) "late" type Ia endoleaks (eg, newly detected type Ia endoleak identified on postoperative CTA after the initial 30 day follow-up interval) were detected with a median–IQR time of detection 32.9–25.7 months (12.3–65.2).

Table 5. Morbidity and Mortality Details.

	n	%
30 d morbidity		
Patients experienced 30 d complication	27	10.1
Total 30 d complications	39	14.6
Cardio-respiratory failure[a]	15 (4[b])	5.6
Intestinal ischemia	1 (1[b])	0.4
Temporary renal failure	9	3.4
Permanent dialysis	1	0.4
Renal hematoma	3	1.1
Stroke[a]	3	1.1
Limb ischemia	2	0.7
Access/wound	5	1.9
Total 30 d mortality	5	1.9
Cardio-respiratory failure	4	1.5
Intestinal ischemia	1	0.4
Overall mortality	56	21.0
Overall CHEVAR-related mortality	6[c]	2.2
Overall not-related mortality	50	18.8
Cardio-respiratory failure	24	9.0
Neoplasmatic disease	12	4.5
Unknown[d]	10	3.7
Sepsis	3	1.1
Stroke	1	0.4

Categorical data are given as the counts (percentage).
Abbreviations: CHEVAR, chimney endovascular abdominal aortic aneurysm.
[a]Seven patients experienced mainly respiratory failure, 8 mainly cardiac failure/ischemia and 1 patient of them had also a stroke.
[b]Number of patients died during the 30 d period.
[c]Additionally to the 30 d mortality, 1 patient who was set in persistent dialysis due to renal CG occlusion died during follow-up.
[d]Unknown cause of death, no hospitalization, no autopsy performed and no symptoms of aneurysm's related pathology.

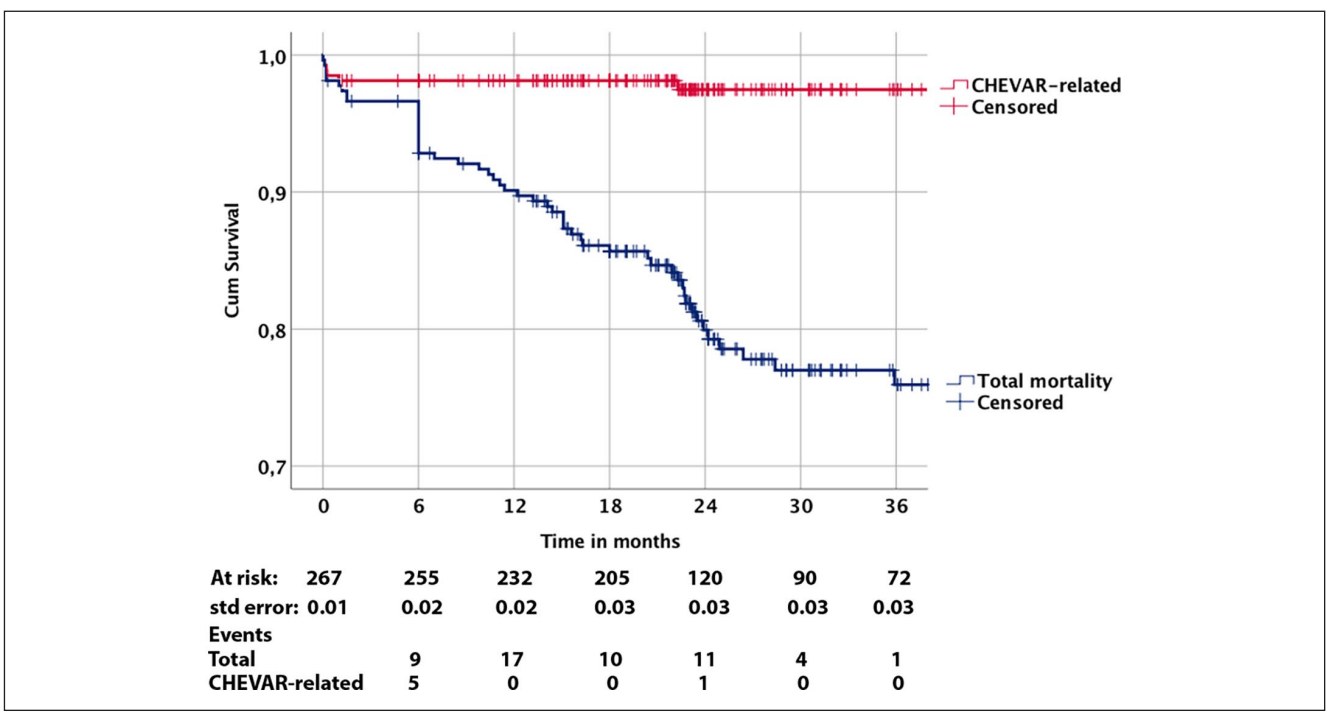

Figure 2. Mid-term total and CHEVAR-related mortality.

Table 6. Early (Intraoperative and 30 d) Results.

	n	%
Chimney related endoleak/PSZF (n=267)		
Index procedure		
Initial completion angiogram		
Endoleak type Ia and/or proximal migration[a]	21	7.9
Primary unplanned treatment of Ia endoleak	19	7.1
Kissing dilatation of aortic and CGs	15	5.6
Proximal cuff placement	4	1.5
Gutter's endoleak remained for observation	2	0.7
30 d		
Persistent endoleak type Ia at 30 d	0	0.0
CGs patency (n=442)		
Index procedure		
Intentional splanchnic vessel coverage	6	1.4
Total intraoperative CGs occlusions	7	1.6
30 d		
Total 30 d CGs occlusions	14	3.1
Renal arteries[b]	13	2.9
Flank pain/asymptomatic	5/5	1.1/1.1
Acute renal failure	2	0.5
SMA	1	0.2
Non CHEVAR-related endoleaks (n=267)		
Endoleak Ib	2	0.7
Endoleak type II	29	10.9
Endoleak type III/IV	1/1	0.4/0.4
Total non CHEVAR-related endoleaks	33	12.4
Other intraoperative complications (n=267)	6	2.2
Renal parenchymal hematoma	3	1.1
Access vessel limb ischemia[c]	2	0.7
Access vessel hematoma	1	0.4

Categorical data are given as the counts (percentage).
Abbreviations: CG, chimney graft; CHEVAR, chimney endovascular abdominal aortic aneurysm; PSZF, proximal sealing zone failure.
[a]One intraoperative aortic graft's migration without evidence of type Ia endoleak was treated with additional proximal aortic cuff placement.
[b]One patient experienced bilateral occlusion.
[c]One left upper limb ischemia was treated with brachio-brachial bypass and 1 left lower limb ischemia was treated with femoral embolectomy.

Notably, 1 of these late type Ia endoleaks occurred in a patient who had a documented intraoperative type Ia endoleak that underwent cuff extension and had absence of endoleak on the 30 day postoperative CTA. All other intraoperative Ia endoleaks, including the 2 considered "spontaneously sealed" at first month CTA, remained sealed at mid-term. Therefore, 18 of the late type Ia endoleaks occurred in patients without previously detected endoleak (either intraoperatively or on the initial 30 day postoperative CTA).

In 8 late type Ia endoleaks, the maximum AAA diameter remained stable and the patients remained under serial surveillance without re-intervention. Three patients were deemed unfit for secondary intervention despite documented increases in postoperative AAA diameter and remained under surveillance. Finally, a successful re-intervention procedure for late type Ia endoleak was performed in 8 patients. In 3 of these patients, proximal aortic cuff extension occurred while 1 patient underwent aortic cuff implantation combined with additional CG placement. Three late Ia endoleaks were treated with onyx embolization, while 1 patient underwent open surgical conversion and removal of the CHEVAR. Additionally, 3 patients were diagnosed with endotension (eg, no identified endoleak with continued AAA sac expansion during follow-up) and were also classified as type Ia endoleaks, as defined by this analysis. One of them was treated by open conversion and 2 remained under serial observation. Table 7 further summarizes the data surrounding proximal sealing zone failures in mid-term follow-up.

Chimney Failure. A total of 23 events (5.2% of 442 subjects, Table 7) were classified as CG failures after the 30 day follow-up interval and these were observed in 21 (7.9%)

Table 7. Mid-Term Results.

Proximal sealing zone failures (PSZF)	Preoperative (n)	Follow-up (%)
Persistent type Ia endoleak	19	7.1
Recurrence of "sealed" at 30 d imaging	1	0.4
"New" Ia endoleaks	18	6.7
Stable AAA's diameter—conservative/observation	8	3.0
Secondary procedures in increased AAA's diameter	8[a]	3.0
Poor clinical condition in increased AAA's diameter	3	1.1
Endotension	3	1.1
Stable AAA's diameter—conservative/observation	1	0.4
Open conversion	1	0.4
Poor clinical condition in increased AAA's diameter	1	0.4
Total	22	8.2
Total PSZF-related re-interventions	9	
Endovascular re-interventions	7	2.6
Open conversions	2	0.7
CGs occlusions in 442 CGs (in 267 patients[c])	23 (21)	5.2 (7.9)
Renal artery (percentage in 375 CGs)	20	5.3
Superior Mesenteric artery (percentage in 54 CGs)	3	5.5
Treatment for CGs's patency (percentage in 267 patients)		
Conservative treatment	12	2.7
Endovascular re-interventions	7	2.6
Open conversions	2[b]	0.7
AAA's maximum diameter *r*[d] (mm)	61.0–15.0	56.0–17.0

Categorical data are given as the counts (percentage).
Abbreviations: AAA, abdominal aortic aneurysms; CG, chimney graft; PSZF, proximal sealing zone failure.
[a]One open re-intervention.
[b]The 2 open re-interventions were 1 iliac-renal and 1 aorto-mesenteric bypass.
[c]Two patients experienced bilateral renal artery occlusions.
[d]Continuous data with skewed distribution are presented as median and interquartile range. p value of difference <0.001.

patients. Sixteen of these patients experienced a single renal artery CG occlusion (8-left and 8-right renal). Additionally, 2 patients experienced bilateral renal CG occlusion and the remaining 3 patients experienced SMA CG occlusion. Twelve clinically silent CG occlusions, including the 3 cases of SMA, were eventually diagnosed at scheduled imaging follow-up and treated conservatively. Seven patients underwent a secondary endovascular re-intervention to address late CG failure. These remedial procedures resulted in successful recanalization of the CG in 3 patients. Additionally, an open revascularization procedure was performed in 2 patients. Secondary open and endovascular re-interventions remained patent during follow-up, with full recovery of kidney's function.

Overall (Early and Mid-Term) Secondary Endpoints Evaluation

The total follow-up primary and secondary type Ia endoleak/endotension rates were 8.2% (n=22) and 5.6% (n=15), respectively. Figure 3 demonstrates the Kaplan–Meier analysis of primary and secondary freedom from persistent type Ia endoleaks/endotension at 3 years and the relevant estimated cumulative rates were $93.0\pm0.2\%$ and $98.0\pm0.5\%$, respectively. Thirty-four (12.8%) patients experienced some form of visceral vessel occlusion (28 CG occlusions and 6 had intentional renal artery coverage at index procedure). The total primary and secondary freedom from splanchnic vessels occlusion was achieved in 233 (87.3%) and 241 (90.3%) of patients', respectively. Figure 4 shows the Kaplan–Meier analysis of freedom from primary and secondary CG occlusion or severe stenosis at 3 years. The estimated primary and secondary CG's patency rates were $87.0\pm0.4\%$ and $89.0\pm0.4\%$, respectively.

The primary clinical success, expressed as cumulative freedom from primary and secondary endpoints at 3 years, was achieved in $81.0\pm0.2\%$ of patients and the relevant secondary clinical success, by exclusively endovascular means, was $94.0\pm0.1\%$, Figure 5.

A total of 41 secondary re-interventions were performed in 40 (15.0%) patients and 23 of them were CHEVAR-related re-interventions and were performed in 22 (8.2%) patients. The cumulative freedom from any re-intervention

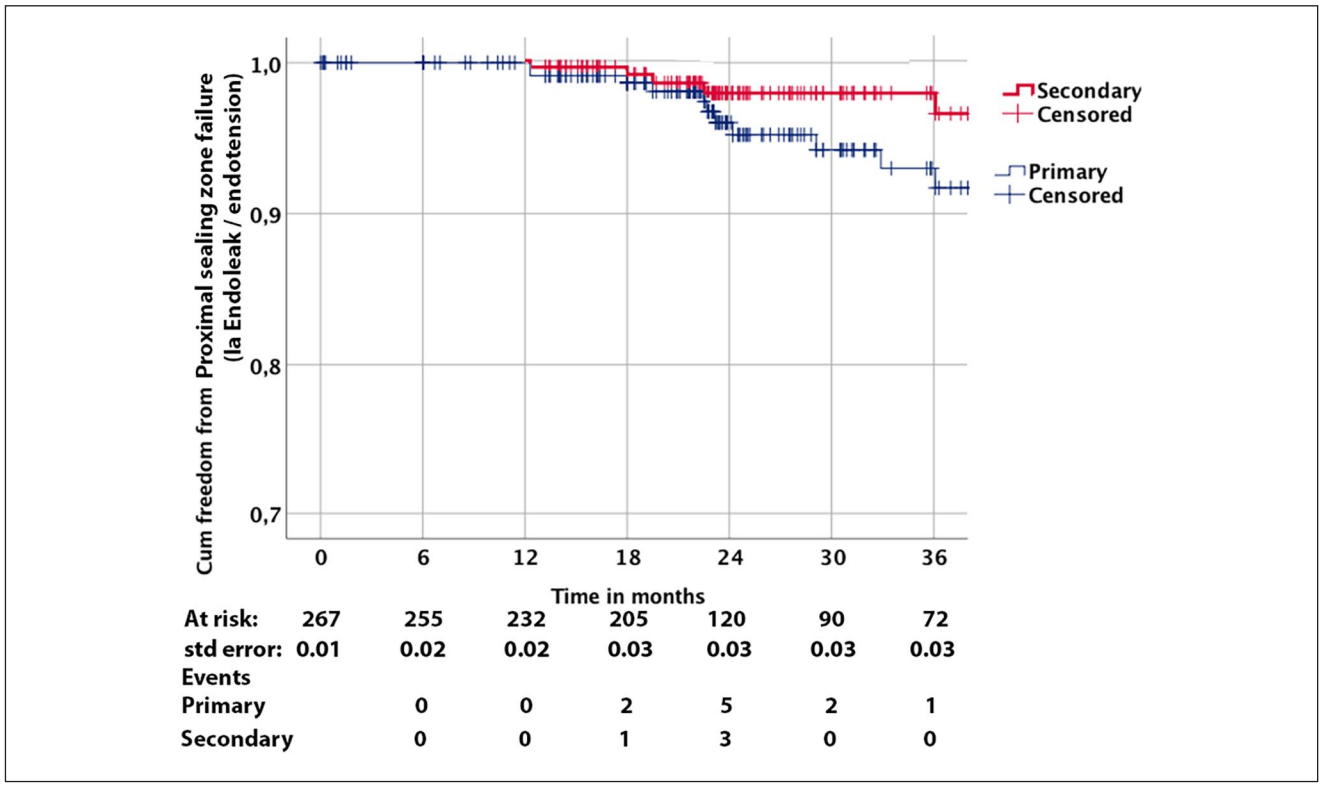

Figure 3. Mid-term freedom from proximal sealing zone failure (type Ia endoleak and/or endotension).

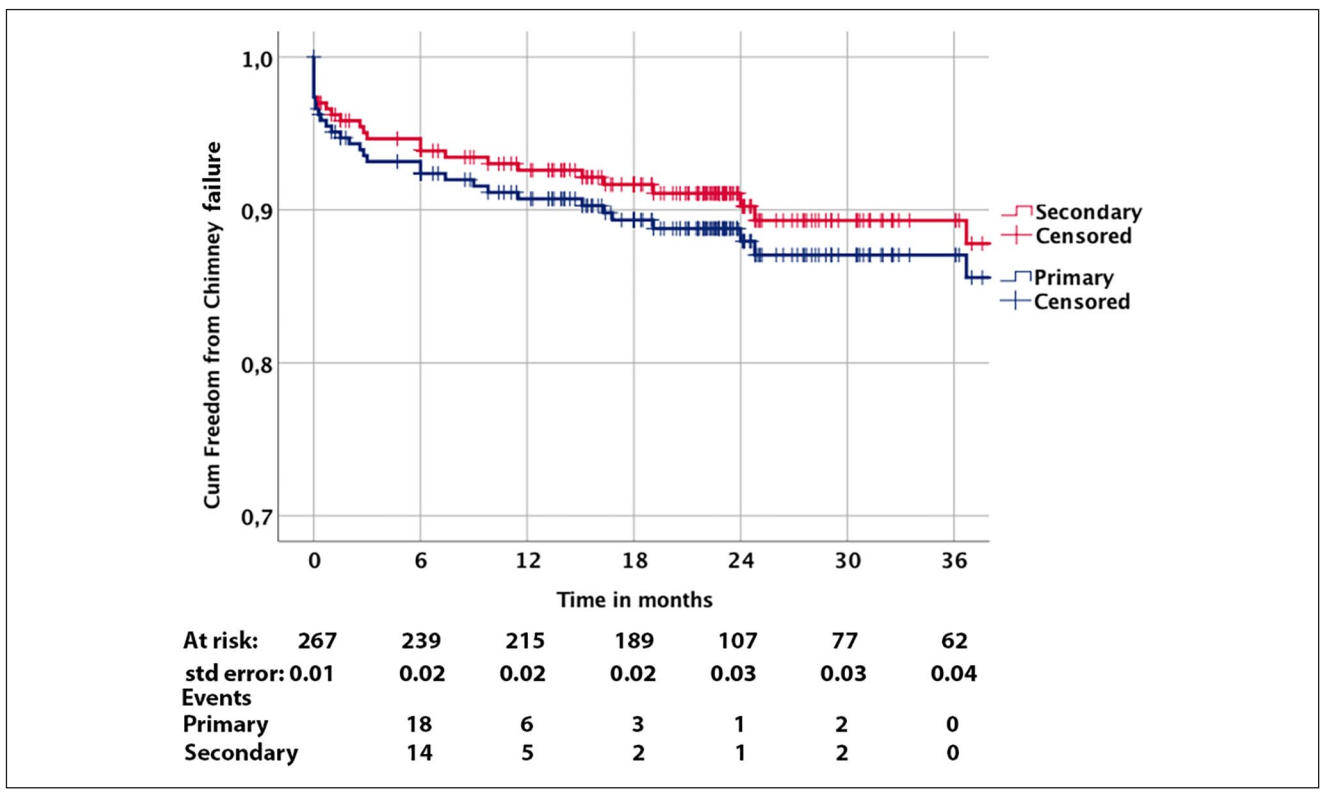

Figure 4. Mid-term freedom from chimney failure [CG or involved splanchnic vessel occlusion and/or high-grade (>70%) stenosis].

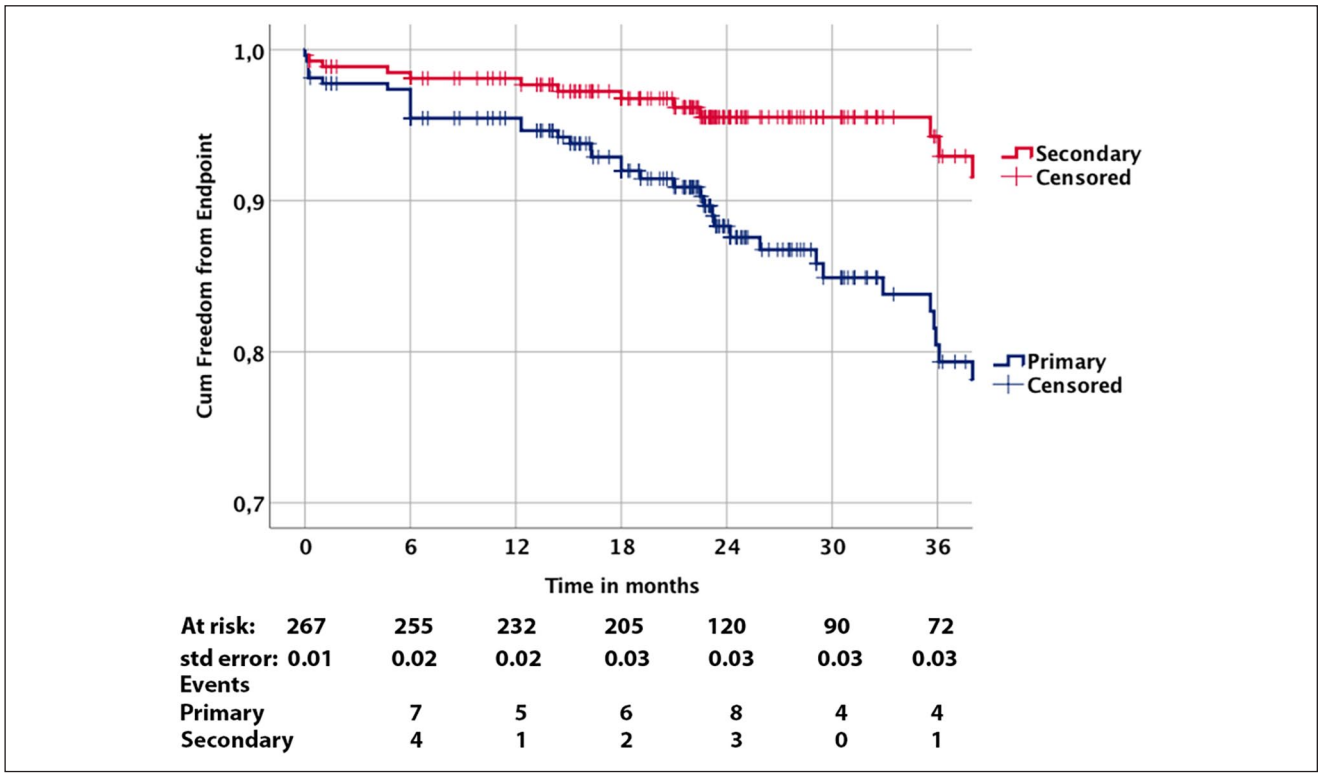

Figure 5. Mid-term clinical success (freedom from any primary or secondary endpoint).

and CHEVAR-related re-intervention was 83.0±0.6% and 89.0±0.6%, respectively (Figure 6).

Discussion

Surgical treatment of pararenal AAA (PAAs) has the mandatory requirement to revascularize involved renal-visceral vessels, increasing technical complexity of the procedure. Traditional open aortic repair requires suprarenal aortic cross-clamping, which can be associated with significant alterations in cardiovascular physiology and renal perfusion, resulting in increased perioperative morbidity and mortality rates.[9,10] Notably, fenestrated endovascular repair (FEVAR) significantly decreases morbidity and mortality of PAAs and is now recognized to be a reliable and durable alternative to open repair, especially in high-risk patients.[11,12] However, FEVAR has several anatomic restrictions related to access vessel and pararenal aortic neck morphologic characteristics which may not be a suitable option for elective treatment of high-risk PAA patients without favorable anatomy.[13–15]

Over the last decade, CHEVAR has been increasingly applied in the treatment complex aneurysm and other pararenal aortic pathologies. Numerous studies[3,16,17] have demonstrated favorable results of CHEVAR in the treatment of aortic arch and pararenal aortic pathologies. However, a major shortcoming of these previous publications is that they have failed to clarify what role CHEVAR has in the elective setting. Accordingly, this technique has thus far been accepted and/or recognized as a reasonable endovascular alternative to FEVAR, but mainly for urgent/non-elective cases.[4,5,18] The primary criticism of prior peer reviewed evidence on this topic has been that these reports included mixed populations of various aortic pathologies and different clinical presentations. Importantly, dPAAs represent the primary indication in the vast majority of elective procedures reported in peer reviewed literature focusing on management of complex endovascular aneurysm repair.[19] Accordingly, to evaluate CHEVAR's role in elective dPAA management, a focused analysis that provides a transparent accounting of relevant early and late endpoints, is required.

To the best of our knowledge, the current study represents the first report in the peer-reviewed literature that highlights elective CHEVAR results for dPAA using a large, multicenter, and multi-national registry and reports mid-term outcomes. The cumulative CHEVAR-related mortality at 3 years was ~2%, highlighting safety and durability in this cohort of high-operative risk dPAA patients. Traditionally, the "gutter-associated" type Ia endoleak was considered the Achilles' heel of CHEVAR and a source of great concern and significant criticism of the procedure.[20] In our series, all but 1 gutter-associated type 1a endoleak

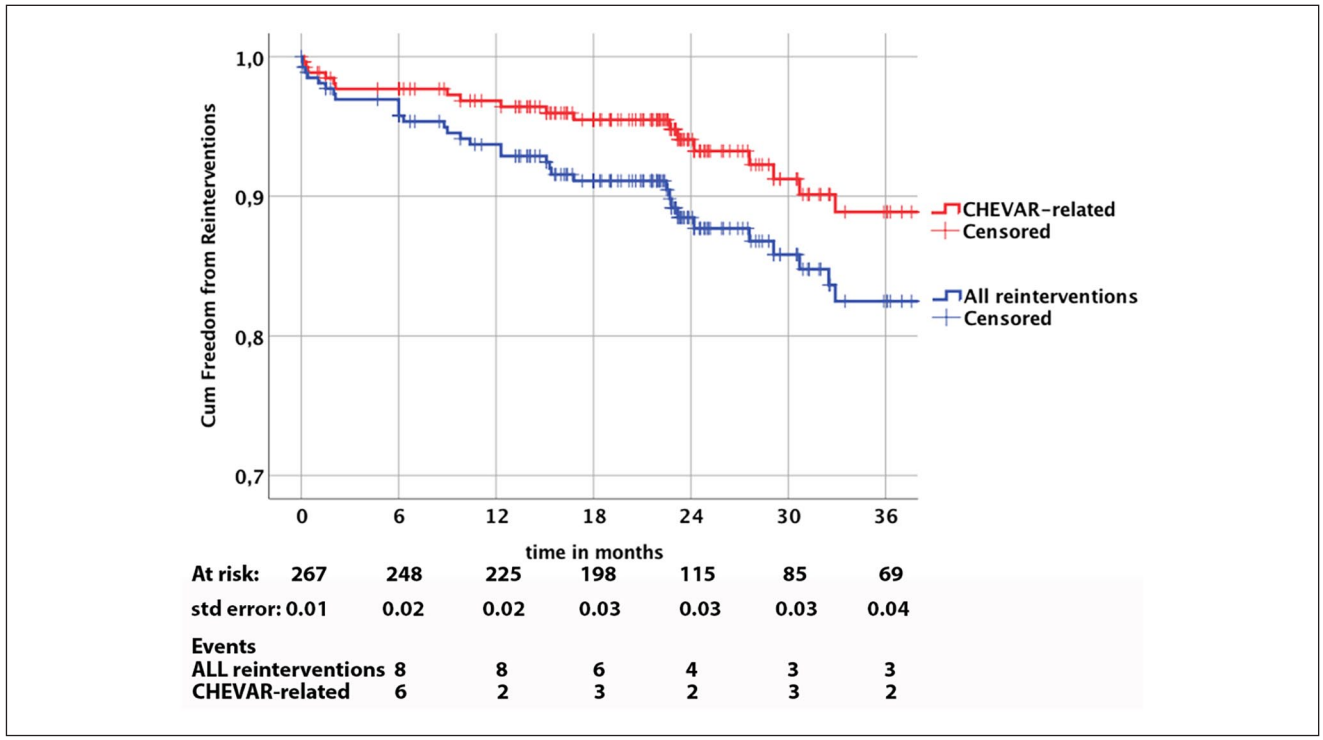

Figure 6. Mid-term freedom from re-interventions (CHEVAR-related and total).

spontaneously sealed during follow-up corroborating a benign natural history of this finding. On the other hand, 18 patients with no intraoperative endoleak on completion angiogram developed late type Ia endoleak after the initial 30 day perioperative period at the mid-term follow-up. Of note, median time to development of late type Ia endoleak detection was 35.3 months with a minimum at 12.3 months and maximum interval at 65.2 months, which underscores the mandatory need for life-long imaging surveillance, similar to the other endovascular aortic therapies.

The overall mid-term freedom from primary persistent type Ia endoleak/endotension was 93.0%, which is analogous to reported rates after conventional EVAR and the relevant secondary rate was 98.0%, which is very close to the reported FEVAR results.[21,22] Evaluating the efficacy of CHEVAR, the second issue that emerges is chimney vessel patency and the clinical consequences of CG occlusion. The clinical course of chimney vessel occlusion varies along a spectrum from being completely asymptomatic, which usually remain undiagnosed until the next follow-up imaging, to profound and potentially fatal splanchnic ischemia, requiring emergent secondary re-intervention. The estimated primary and secondary CG patency rates of current study were 87.0% and 94.0% at 3 years. The majority (n=22, 65%) of splanchnic vessels occlusions were completely asymptomatic (n=17) or had mild symptoms (n=5) without further clinical consequences. Additionally, new onset dialysis, which has a profound impact on a patients' post-operative quality of life,[23] was very low (n=3, 1.1%). Similarly, the incidence of death related to a CG occlusion event was 0.8% (n=2).

The results of the current analysis are similar to those reported for other total endovascular solutions in treatment of dPAAs[22,24–26] and are in accordance with reported results from large single institution series.[27] Notably, elective CHEVAR for dPAA patients has previously been reported to be cost effective since it employs equipment and techniques that are immediately available and familiar to most endovascular surgeons at centers already performing standard EVAR.[28–30] Importantly, CHEVAR has previously been reported to have fewer access vessel and aortic neck anatomic restrictions making it applicable in a significant number of patients.[3] Accordingly, the present findings justify an expanded role for CHEVAR in the elective management algorithm for dPAA.

The results of the current analysis should be interpreted within the context of its limitations. No specific treatment protocol or specific device combination was employed uniformly by all centers. Similarly, the threshold for re-intervention was not pre-determined, so surgeon judgment certainly influenced the reported results. Additionally, the lack of randomization and comparison to an open surgical and/or FEVAR cohort makes it difficult to derive robust conclusions. Lastly, considering that patients enrollment completed in 2014, the follow-up and reported results are limited to the relatively small period of mid-term. However,

the study is physician driven and not funded from industry with obvious difficulties to gather data of further follow-up from the 13 transatlantic participating centers. Hence, we consider that the experience reported here further bolsters the standing of CHEVAR in the treatment armamentarium of complex aneurysm disease.

Mid-term results of this transatlantic multicenter series of patients with dPAA showed that elective CHEVAR was a safe, effective and durable technique with comparable outcomes to other currently endorsed total endovascular solutions. These results support an expanded role of CHEVAR in elective dPAA management and justify development of randomized trials designed to compare differences between FEVAR and open surgical repair in this select group of patients.

Author's Note

Collaborators:

PERICLES investigators: Mario Lachat, Gergana T. Taneva, Apostolos G. Pitoulias, Ronald L. Dalman, Kenneth Tran, Felice Pecoraro, Sven Seifert, Mirko Esche, Daniele Gasparini, Paolo Frigatti, Roberto Adovasio, Fabio Pozzi Mucelli, Scott M. Damrauer, Edward Y. Woo, Adam Beck, David Minion, Juha Salenius, Velipekka Suominen, Nicola Mangialardi, Sonia Ronchey, Gaspar Mestres, Vincent Riambau, and Nilo J. Mosquera.

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ORCID iDs

Georgios A. Pitoulias https://orcid.org/0000-0002-6862-2709
Mario D'Oria https://orcid.org/0000-0002-7156-7827
Giovanni Torsello https://orcid.org/0000-0001-7513-5063

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