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Collected world experience about the performance of the snorkel/chimney endovascular technique in the treatment of complex aortic pathologies: the PERICLES registry

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Abstract: OBJECTIVES: We sought to analyze the collected worldwide experience with use of snorkel/chimney endovascular aneurysm repair (EVAR) for complex abdominal aneurysm treatment. BACKGROUND: EVAR has largely replaced open surgery worldwide for anatomically suitable aortic aneurysms. Lack of availability of fenestrated and branched devices has encouraged an alternative strategy utilizing parallel or snorkel/chimney grafts (ch-EVAR). METHODS: Clinical and radiographic information was retrospectively reviewed and analyzed on 517 patients treated by ch-EVAR from 2008 from 2014 by prearranged defined and documented protocols. RESULTS: A total of 119 patients in US centers and 398 in European centers were treated during the study period. US centers preferentially used Zenith stent-grafts (54.2%) and European centers Endurant stent-grafts (62.2%) for the main body component. Overall 898 chimney grafts (49.2% balloon expandable, 39.6% self-expanding covered stents, and 11.2% balloon expandable bare metal stents) were placed in 692 renal arteries, 156 superior mesenteric arteries (SMA), and 50 celiac arteries. At a mean follow-up of 17.1 months (range: 1-70 months), primary patency was 94%, with secondary patency of 95.3%. Overall survival of patients in this high-risk cohort for open repair at latest follow-up was 79%. CONCLUSIONS: This global experience represents the largest series in the ch-EVAR literature and demonstrates comparable outcomes to those in published reports of branched/fenestrated devices, suggesting the appropriateness of broader applicability and the need for continued careful surveillance. These results support ch-EVAR as a valid off-the-shelf and immediately available alternative in the treatment of complex abdominal EVAR and provide impetus for the standardization of these techniques in the future.

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Collected World Experience About the Performance of the Snorkel/Chimney Endovascular Technique in the Treatment of **Complex Aortic Pathologies**

The PERICLES Registry

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Objectives: We sought to analyze the collected worldwide experience with use of snorkel/chimney endovascular aneurysm repair (EVAR) for complex abdominal aneurysm treatment.

Background: EVAR has largely replaced open surgery worldwide for anatomically suitable aortic aneurysms. Lack of availability of fenestrated and branched devices has encouraged an alternative strategy utilizing parallel or snorkel/chimney grafts (ch-EVAR).

Methods: Clinical and radiographic information was retrospectively reviewed and analyzed on 517 patients treated by ch-EVAR from 2008 from 2014 by prearranged defined and documented protocols.

Results: A total of 119 patients in US centers and 398 in European centers were treated during the study period. US centers preferentially used Zenith stent-grafts (54.2%) and European centers Endurant stent-grafts (62.2%) for the main body component. Overall 898 chimney grafts (49.2% balloon expandable, 39.6% self-expanding covered stents, and 11.2% balloon expandable bare metal stents) were placed in 692 renal arteries, 156 superior mesenteric arteries (SMA), and 50 celiac arteries. At a mean follow-up of 17.1 months

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(range: 1-70 months), primary patency was 94%, with secondary patency of 95.3%. Overall survival of patients in this high-risk cohort for open repair at latest follow-up was 79%.

Conclusions: This global experience represents the largest series in the ch-EVAR literature and demonstrates comparable outcomes to those in published reports of branched/fenestrated devices, suggesting the appropriateness of broader applicability and the need for continued careful surveillance. These results support ch-EVAR as a valid off-the-shelf and immediately available alternative in the treatment of complex abdominal EVAR and provide impetus for the standardization of these techniques in the future.

Keywords: abdominal aortic aneurysm, endovascular, fenestrated, thoracoabdominal, vascular

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he snorkel/chimney technique is an endovascular therapeutic modality for branch revascularization in complex aortic pathologies that has gained increasing popularity since the first publications in 2003 and 2007.^{1,2} These techniques have emerged from the basic idea of creating a "snorkel/chimney" conduit from available off-theshelf stents deployed into target visceral branches from a parallel course adjacent to the main intra-aortic stent-graft. Initially proposed as a bailout technique for inadvertent coverage or emergent situations, this strategy has since been employed electively in juxta- or pararenal cases with the goal to preserve or restore normal blood flow into the involved branch or branches. $^{1-10}$

The current body of published literature on snorkel/chimney endovascular aneurysm repair (ch-EVAR) consists mainly of case reports and single center series with limited numbers of patients and follow-up. Furthermore, the majority of patients were being treated for a wide variety of aortic pathologies using nonstandardized offthe-shelf devices and follow-up protocols. As a result, critics of the snorkel/chimney approach as a mainstream strategy claim that it remains difficult to obtain a clear picture of ch-EVAR outcomes and its potential applications. With fenestrated/branched solutions slowly being approved by the Food and Drug Administration as a purposespecific and on-label solution to complex EVAR, concerns with ch-EVAR regarding overall technical success, gutter-related type Ia endoleaks, chimney stent patency, long-term renal dysfunction, and ch-EVAR durability make this approach an oft-debated treatment strategy. The purpose of this study was to collect and analyze a large sample of the world experience with ch-EVAR from centers with significant experience and standardized protocols for operative strategy and follow-up to provide the latest evidence regarding this treatment option for complex abdominal aortic aneurysms.

METHODS

The study was conducted to evaluate the **PER** formance of the chImney technique for the treatment of Complex aortic pathoLogiES

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(PERICLES registry). It complied with the principles of the Declaration of Helsinki and the data collection, and acquisition was approved by the local ethics committee and respective institutional review boards from the individual sites participating in the registry. A retrospective chart and imaging review was then performed and entered in a de-identified fashion into a central data repository. After a systematic review of the literature had been published as to early results of ch-EVAR,9 centers having reported case series were contacted and asked to participate in the PERICLES registry. Participating centers (see Supplemental Digital Content Appendix, available at http://links.lww.com/SLA/A836) were required to have treated at least 10 patients with complex aortic pathologies by the snorkel/chimney technique. All commercially available abdominal endografts in different combinations with chimney grafts were included in the present study. Patients with thoracic aneurysms, aortic dissections, or extensive thoracoabdominal aneurysms with involvement of the supradiaphragmatic thoracic segment were excluded. Clinical and radiological data were reviewed and analyzed on the basis of protocols with predefined parameters as to comorbidities, classification, and description of the various pathologies, intraoperative variables, and relevant clinical outcome variables.

Indications

All patients considered candidates for ch-EVAR at each institution were deemed to be high-risk candidates for open surgical repair. This category often included patients with several cardiovascular or anatomic comorbidities such as active chronic obstructive pulmonary disease, poorly controlled congestive heart failure, symptomatic coronary artery occlusive disease, American Society of Anesthesiologists score of 3 or more, previous myocardial infarction, coronary stent or bypass, and/or prior open abdominal aortic repair. In 3 of 13 participating centers, fenestrated/branched endografts (f-EVAR) were available, and the included ch-EVAR cases in this registry were based on surgeon preference, the need for urgent treatment, and/or anatomical unsuitability for f-EVAR such as presence of severe angulation of the neck or severe calcification, and stenosis or angulation of the iliac vessels. Because the PERICLES registry was an individual institution registry data collection, details about outcomes stemming from other concurrent strategies at each individual center were not obtained.

Definitions

Complex aortic anatomy has some heterogeneity, and we defined juxtarenal pathologies to include degenerative aneurysms or penetrating atherosclerotic ulcers up to the level of renal arteries, type Ia endoleaks after standard EVAR, and para-anastomotic aneurysms after previous open aortic repair. Pararenal pathology was defined as aneurysm dilation up to the level of the superior mesenteric artery. There was a small number of type IV thoracoabdominal aneurysms included in the PERICLES with slight dilation at the level of the SMA that did not extend to the diaphragm.

Patients' risk factors and demographics and outcomes were collected and adhered to the reporting standards of the Society for Vascular Surgery.¹¹ Chimney graft-related reinterventions were defined as secondary procedures performed to treat high-grade stenosis (>70%) confirmed by angiography, occlusions of the chimney grafts, or endoleaks around chimney grafts, requiring additional proximal treatment. Chimney graft patency was defined as the absence of occlusion on postoperative imaging and perfusion of the target organ (most often the kidney). Technical success was defined as successfully completed ch-EVAR (patent endograft and involved target vessels without evidence of type I or III endoleak on the basis of the classification from Pecoraro et al). 10

Endpoints

Primary endpoints included aneurysm sac diameter regression, chimney graft patency, and freedom from endoleak. Secondary endpoints included all-cause mortality, aneurysm-related mortality, chimney graft-related reinterventions, and renal function. Follow-up data included events during the initial hospitalization and the postoperative period up to the date of the last available radiological imaging. Data on clinical status, duplex ultrasound imaging, and contrast computed tomographic scan/magnetic resonance image were reviewed and collected for each patient.

Acute and Chronic Renal Function Changes

For acute renal deterioration, we utilized the consensus definition of acute kidney injury (AKI) defined by the RIFLE system, proposed by the Acute Dialysis Quality Initiative group, which stages AKI into 5 grades: risk (R), injury (I), failure (F), loss (L), and end stage (E).12 In detail, Risk was defined as a 1.5x relative increase in serum creatinine from baseline or a decrease of glomerular filtration rate (GFR) more than 25% compared with the baseline. Injury was defined as a 2x increase in serum creatinine or GFR decrease more than 50%; failure 3x increase in serum creatinine or GFR decrease more than 75%. Loss of kidney function is for more than 4 weeks and end-stage kidney disease was defined as compete loss of kidney function for more than 3 months.

For chronic real deterioration, the widely employed chronic kidney disease (CKD) staging system developed by the National Kidney Foundation was used with CKD stages on the basis of estimated GFR. Stage 1 was defined as GFR more than 90 mL/min/1.73 m² and stage 2 as mildly reduced kidney function with a GFR value between 60 and 89. Stage 3A and 3B reflect moderately reduced kidney function, with a GFR between 45 and 59 (stage 3A) or 30 and 44 (stage 3B). Stage 4 was associated with severely reduced kidney function (GFR 15-29) and stage 5 was defined as very severe or end-stage kidney failure with a GFR of less than 15.

Statistical Analysis

Descriptive statistics were used to assess study demographics, comorbidities, and outcome variables as appropriate. Student ttest and Pearson χ^2 tests were used to analyze relationships between continuous and categorical variables, respectively. Comparison of pre-and postoperative ch-EVAR maximum aneurysm diameters was performed with the paired t test as appropriate. Freedom from renal decline was evaluated using Kaplan-Meier methods. A P value of less than 0.05 was considered statistically significant for all analyses. Statistical analysis was performed using STATA 12.0 software (StataCorp LP, College Station, TX).

RESULTS

A total of 119 patients were treated at participating US centers and 398 in Europe from 2008 to 2014. US centers used Zenith stentgrafts (Cook Medical, Bloomington, IN) in the majority of cases (54.2%) whereas the Endurant stent-graft (Medtronic, Santa Rosa, CA) was most commonly used at the European centers (62.2%). Overall, Endurant was used in 49.5% (n = 260 patients), and Zenith in 17.3% (n = 91). Tables 1, 2, and 3 summarize the treated pathologies, cohort demographics, anatomic characteristics, relevant intraoperative variables, and the abdominal and chimney devices used.

In all, 898 target aortic branch vessels were revascularized using chimney grafts. The mean number of chimney grafts placed was 1.73 per patient, with 692 renal chimneys, 156 SMA chimneys, and 50 celiac chimneys inserted. Of these, 49.2% (n = 442) were balloon-expandable covered stents [Advanta (iCAST) V12, Maquet, New Hudson, NJ] and 39.6% (n = 355) were self-expanding covered

TABLE 1. Aortic Pathologies Treated With the Snorkel/Chimney Technique

Total patients	517
European centers $(N = 9)$	398
United States centers $(N = 4)$	119
Disease, n (%)	
Degenerating aneurysm	404 (78.1)
Penetrating ulcer	12 (2.3)
Type 1a endoleak from prior EVAR	45 (8.7)
Para-anastomotic aneurysm from prior open AAA repair	43 (8.3)
Intramural hematoma/type B dissection	13 (2.5%)
Classification, n (%)	
Juxtarenal AAA	360 (69.6)
Suprarenal AAA	129 (25.0)
Type IV TAAA	28 (5.4)
Clinical status, n (%)	
Asymptomatic	415 (80.3)
Symptomatic	52 (10.0)
Rapidly growing	21 (4.1)
Rupture	29 (5.6)

AAA indicates abdominal aortic aneurysm; EVAR, endovascular aneurysm repair; TAA, thoraco-abdominal aneurysm.

TABLE 2. Patient Characteristics and Demographics

Age, mean \pm SD (range), yr	$75.2 \pm 7.8 (48-93)$
Sex	` '
Male (%)	83.7
Female (%)	16.3
ASA class, n (%)	
I	0 (0)
II	18 (3.5)
III	293 (56.6)
IV	2404 (39.5)
V	2 (0.4)
Diabetes	112 (21.8)
Hyperlipidemia	315 (61.1)
Hypertension	455 (88.2)
CAD	276 (53.5)
COPD	216 (42.0)
PAD	85 (81.2)
Smoking history (%)	
None	182 (36.5)
Quit >6 mo	214 (42.9)
Quit <6 mo	19 (3.8)
Current smoker	84 (16.8)
CHF	186 (40.1)
Chronic renal insufficiency (GFR <60)	173 (39.7)
Hemodialysis	11 (2.5)

CAD indicates coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; PAD, peripheral arterial disease.

stents (Viabahn, Gore Medical, Flagstaff, AZ). Balloon-expandable bare-metal stents were used as the primary chimney stent in 11.2% of the cases (n = 101). Bare-metal nitinol stents were used to reline the inside of a covered chimney stent in 25.4% (220/898) of the cases, most often the Viabahn.

The mean preoperative diameter of the juxtarenal aneurysms treated was 65.9 ± 16.5 mm (range: 48–135 mm), with a mean preoperative proximal neck length of 4.8 ± 7.4 mm (range: 0–13 mm), making them unsuitable for traditional EVAR. The snorkel/chimney strategy increased the theoretical neck/seal length to 21.1 \pm 12.7 mm (range: 9–43 mm). Intraoperative characteristics are summarized in Table 3. A type Ia endoleak was noted intraoperatively in 41 patients

TABLE 3. Juxtarenal Aneurysm Anatomic Characteristics, Aortic and Branch Stent-grafts, and Intraoperative Variables

Preoperative anatomy	
Maximum aneurysm diameter	65.9 ± 216.5
(mm), mean \pm SD	
Minimum aneurysm diameter	55.0 ± 17.2
(mm), mean \pm SD	
Infrarenal neck diameter (mm),	26.4 ± 4.8
mean \pm SD	
Infrarenal neck length (mm), mean	4.8 ± 7.4
\pm SD	24.4.4.2.5
Snorkel/chimney neck length,	21.1 ± 12.7
$mean \pm SD$	
Device, n (%)	250 (40.5)
Endurant	260 (49.5)
Zenith	91 (17.3)
Excluder	75 (14.3)
Gore TAG	28 (5.3)
Jotec	17 (3.2)
Zenith TX2	11 (2.1)
Valiant	31 (6.0)
Talent	4 (0.7)
Total chimney grafts, n	898
Right renal	342
Left renal	316
Accessory renal	34
SMA	156
Celiac	50
Types of chimney grafts (%)	442 (42.2)
Balloon-expandable covered	442 (49.2)
Self-expanding covered	355 (39.6)
Balloon-expandable bare metal	101 (11.2)
Use of bare metal nitinol stents	220 (25.4)
"endolining" (as percentage of	
cohort)	
Intraoperative variables	
Operative time (min), mean \pm SD	233.0 ± 98.7
Fluoroscopy time (min), mean \pm SD	60.83 ± 38.6
Contrast volume (mL), mean \pm SD	162.4 ± 59.6
SMA indicates superior mesenteric artery.	

(7.9%). Corrective treatment consisted of kissing-balloon dilatations of the aortic stent-graft and chimney graft in 21, and additional proximal aortic cuff placement in 5 patients. Fifteen patients (2.9%) exhibited a persistent type Ia endoleak despite attempted corrective measures. Thus, technical success was achieved perioperatively in 502 of the 517 cases (97.1%).

The 30-day mortality was 4.9% (25/517) for the entire cohort. Of note, 29 patients had ch-EVAR for ruptures, with a 30-day mortality of 24.1% (n = 7), making the elective 30-day mortality rate 3.7%(18/488). Late mortality was 15.5% at longest follow-up (80/517). Four procedure-related deaths were reported (0.7%). Three were due to bowel ischemia and 1 related to graft infection. Otherwise, heart failure (n = 23) and cancer (n = 11) were the main unrelated diseases leading to mortality during follow-up. Other causes of death unrelated to the aortic pathology or procedures were pneumonia and sepsis (n = 13) and "poor general health status" (n = 7). The estimated patient survival was 91.3% (range: 88.3%-93.6%), 84.9% (range: 80.1%–88.0%), 77.2% (range: 72.2%–81.5%), and 74.9% (range: 56.1%–79.4%) at 6 months, 1 year, 2 years, and 3 years, respectively (Fig. 1). No patient developed spinal cord ischemia from any etiology. Nine patients (1.7%) had an embolic stroke judged to have been related to the upper-extremity arterial access. All but 1 of these

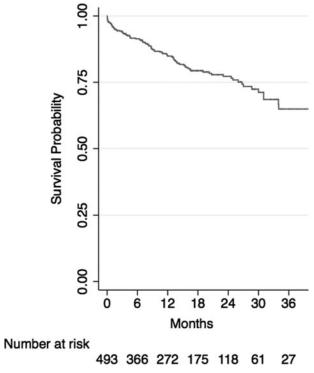


FIGURE 1. Overall survival rate of the patients treated with snorkel/chimney techniques at latest follow-up.

patients had placement of multiple chimney grafts. Thirty-day morbidity included postoperative access-site related issues requiring reintervention for occlusion or pseudoaneurysm in 10 (1.9%) patients, pneumonia in 16 (3.1%) patients, myocardial infarction in 11 (2.1%) patients, and graft infection in 1 (0.2%) patient.

Computed tomographic follow-up imaging showed subsequent resolution of the intraoperative type Ia endoleak in all but 2 cases (0.4%), both requiring open surgical conversion with explantation of the aortic and chimney devices. Three other cases (0.6%) in whom a late-onset type Ia endoleak was detected at 6-month computed tomography were all treated successfully by endovascular means such as "neck lengthening" and placement of additional chimneys. These endoleaks were judged to be gutter-related endoleaks and were eliminated by the successful "neck lengthening" with creation of a longer landing or seal zone. Interestingly, there seemed to be a trend toward the use of a balloon-expandable covered stent having 2-fold reduction in type Ia endoleaks than self-expanding covered stents (P = 0.018).

At a mean imaging follow-up of 17.1 \pm 8.2 months (range: 1-70 months), mean abdominal aortic aneurysm diameter had decreased to 61.2 ± 19.7 mm (P < 0.001 compared with preoperative), with an individual mean sac regression of 4.4 mm \pm 13.1 mm. Overall primary chimney-graft patency was 94.1%. This was not affected whether a balloon-expandable or self-expanding covered stent was used (P = 0.440). As shown in Figure 2, patency was estimated to be 94.9%, 91.8%, 89.2%, and 87.0% at 6 months, 1 year, 2 years, and 3 years, respectively. Late open surgical conversion was necessary due to infection (n = 2), persistent type Ia endoleak (n = 2), and endotension with an urysm enlargement (n = 1). No patient in this registry presented with aortic rupture at latest follow-up. A secondary procedure was also required to attempt reopening occluded chimney grafts (n = 13) and to seal persistent type II endoleaks leading to aneurysm growth of 5 mm or more (n = 5) or a type III endoleak (n = 3). Overall success of these secondary procedures for their intended purpose was 62%, but with no additional morbidity or mortality. This gave an overall second intervention rate of 6.6% at latest follow-up.

Table 4 presents an overview of the postoperative changes in renal function. During the immediate postoperative period, 67 (17.5%) patients experienced some form of AKI by RIFLE criteria. However,

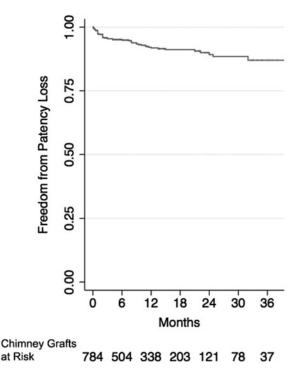


FIGURE 2. Kaplan-Meier estimates showing the patency of snorkel/chimney grafts at latest follow-up.

Preoperative renal disease, n (%)	435 total reporting	
CKD stage 1 or 2	1 0	257 (59.0)
CKD stage 3		158 (36.3)
CKD stage 4		16 (3.7)
CKD stage 5		4 (0.9)
Postoperative acute kidney injury	381 total reporting	67
Risk		40 (59.7)
Injury		9 (13.4)
Failure		10 (14.9)
Loss/end-stage		8 (11.9)
Long-term postoperative renal	381 total reporting	
disease		
CKD stage 1 or 2		193 (50.6)
CKD stage 3		149 (39.1)
CKD stage 4		27 (7.1)
CKD stage 5		12 (3.1)
Change in CKD stage		
−2 Stage		2 (0.5)
−1 Stage		32 (8.4)
0 Stage		263 (69.2)
+1 stage		66 (17.4)
+2 Stage		12 (3.2)
+3 Stage		5 (1.3)

the majority of these patients (n = 40, 59.7%) showed only the lowest grade of acute renal function deterioration. Only 8 of the 67 patients (11.9%, or 1.5% of the entire cohort) who developed AKI required either temporary or permanent dialysis. In midterm follow-up, CKD was found in 83 patients with declining renal function, of whom 66 patients experienced only a 1-stage worsening by CKD level. Twelve (3.2%) and 5 (1.3%) patients experienced a 2- or 3-stage worsening of renal function based on CKD, respectively. When comparing the prevalence of end-stage 5 CKDs pre- and postoperatively, there was an increase from 0.9% (n = 4) to 3.1% (n = 12) of patients with endstage renal failure, requiring long-term hemodialysis. Interestingly, 34 (8.9%) patients experienced a clinically significant improvement in kidney function caused probably by treatment of coexisting renal artery stenoses by the chimney grafts. Five patients (1%) with occlusion of renal chimney grafts suffered significant deterioration of renal function from CKD stage 1/2 to stage 5 and became dialysisdependent. The majority of patients in the cohort (69.2%) experienced no change in CKD stage.

DISCUSSION

The PERICLES registry represents the largest collection of ch-EVAR procedures and patients so far reported in the global literature, reflecting the "real-world" clinical practice involving management of 517 patients in 13 centers with complex juxtarenal and pararenal aortic pathologies. The degree of sac regression postoperatively, the rate of primary patency of these chimney grafts, and the relatively low incidence of type I endoleaks requiring reintervention highlight the value of these techniques and the fact that their wider use may well be warranted.

From the inception and initial descriptions of the snorkel/ chimney strategy, the potential disadvantages and problems have been emphasized with particular attention to the inevitable formation of gutters between the chimney and main endografts and how these could be the cause of type Ia endoleaks. The stent-grafts were never designed to theoretically mold around each other to create a seal, but based on the numerous small case series in the literature, the procedure has worked, although most authors recommend caution until larger series are published. This current study with a wide variety of operators but a generally consistent operative technique reveals that formation of a persistent or new-onset postoperative type Ia endoleaks is rare as long as a sufficiently long (we suggest 20 mm) proximal

landing zone can be created (Figs. 3A-C). The majority of type Ia endoleaks detected intraoperatively resolved with prolonged kissingballoon dilation between the aortic and chimney stent-grafts or additional cuff placement. Should the endoleak persist, close follow-up and monitoring with frequent imaging are required to exclude significant enlargement of the aneurysm sac. If this occurs, further measures such as "neck lengthening" by proximal extensions are employed to create a sufficient sealing zone or even surgical conversion. Future studies are ongoing to try to identify the best combinations of aortic and branch stent-grafts to minimize these theoretical gutter concerns, and this could lower the incidence of type Ia endoleaks even further.14

The present global experience highlights the successful use of off-the-shelf devices used in a parallel graft strategy to create total endovascular solutions for treatment of complex pararenal pathologies involving essential branch arteries. The main alternative strategy to compare our results against is the use of fenestrated grafts for similar lesions. Such fenestrated endografts have been used for many years worldwide, but their wide spread use is relatively early in the United States. Although a direct comparison in a randomized trial will probably never be done, comparison of this current study results with the published literature on fenestrated endografts is important. 15 Available data comparing the techniques before this current series have shown no statistically significant difference between ch-EVAR and fenestrated EVAR (f-EVAR) with regard to technical success, target branch vessel patency, early mortality, type I endoleak, postoperative renal dysfunction, or need for secondary intervention. 16 Still, critics of the ch-EVAR strategy claim that the data are short-term and small in number.

With regard to overall mortality rates after f-EVAR, a pooled 30-day mortality of 2.1% was calculated noted in a recent systematic review¹⁷ that included 9 studies encompassing 629 patients, comparing favorably with our current ch-EVAR study with its 30-day mortality of 4.9% (3.7% if ruptured ch-EVAR was excluded). In an earlier meta-analysis of published reports of ch-EVAR¹⁸ up to 2012, an overall pooled 30-day mortality of 3.4% was noted in 14 studies covering 176 patients. All of these results are acceptable as most patients with juxtarenal aneurysms have significant comorbid medical conditions and the postoperative mortality is often linked to cardiopulmonary issues. Interestingly, when f-EVAR has been compared by propensity matching to series of open surgical repair for juxtarenal aneurysms,





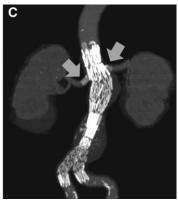


FIGURE 3. A, Coronal section of juxtarenal aortic aneurysm with no neck. Aneurysm thrombus comes right up to left renal artery. Arrows point to each renal artery to be revascularized. B, Intraoperative angiogram showing the balloon molding of the snorkel/chimney grafts (arrows) adjacent to the main body aortic graft. Note that the fabric of the renal grafts is above the aortic graft. C, One-year follow-up computed tomographic-A reconstruction with arrows pointing at snorkel/chimney grafts in good position without kinking and excluding flow into the aneurysm sac (balloon-expandable covered stent Maquet iCast as chimney graft and Cook Zenith bifurcated endograft as abdominal device).

the mortality for f-EVAR is as high as 9.5%, indicating that there is a range of mortality for f-EVAR depending on center experience.¹⁹

In the only comparison of ch-EVAR with open repair at the same institution, the University of Florida group found in matched anatomic patients that even with worse baseline renal and pulmonary function, no difference in 30-day mortality was observed between the 2 treatment groups (4.8% in each).²⁰ Significant reduction in estimated blood loss, transfusion requirements, and length of stay were also noted in the ch-EVAR group. The current study was not meant to be compared with open repair, because the high level of comorbidities made most of the patients in this registry noncandidates for open repair at their respective institutions.

Reinterventions and branch vessel patency are likely the main durability issues of any endovascular treatment, and particularly for ch-EVAR and f-EVAR, these issues are related to type Ia endoleaks and branch patency. Extremely durable results have been published by the world's most experienced f-EVAR center, the Cleveland Clinic, and comparison of these results with those of the current study is worthwhile.²¹ In the Cleveland Clinic article, excellent long-term durability of endovascular repair in 650 patients (1679 target vessels) undergoing abdominal aortic aneurysm repair with branched or fenestrated devices between 2001 and 2010 is reported. The 30-day, 1year, and 5-year freedom from branch reintervention was 98%, 94%, and 84%, respectively. These numbers from this single institution are better than those that our current PERICLES registry is reporting. However, their f-EVAR results are not corroborated by meta-analyses of published reports when more centers are included, suggesting that "real-world" data cannot match those of the most experienced operators. The earlier mentioned meta-analysis of f-EVAR that included 9 studies encompassing 629 patients and a total of 1622 target vessels documented a pooled technical success rate of 90.7% and an estimated reintervention rate of 17.8% during a follow-up period of 15 to 25 months. 17 More importantly, branch vessel patency was found to be 93.2%, renal function decline 22.2%, and all-cause morality 16% at the 15- to 25-month follow-up range, numbers nearly identical to our results from the PERICLES registry.

In a more recent systematic review and meta-analysis of f-EVAR,²² the outcomes of 12 studies involving a total of 776 patients and more than 1728 target vessels calculated a pooled estimate for 30-day mortality of 2.5%, technical success of 92.8%, a short-term 12-month type I endoleak rate of 7.9%, target vessel patency of 94.5%, and a secondary intervention rate of 17.6%. More than 70% of the reinterventions occurred during the first year after f-EVAR, and loss of renal artery patency was the leading reason for reintervention (24.1%). These pooled results clearly highlight the learning curve necessary for f-EVAR or any complex EVAR strategy. They also emphasize that the results from the most experienced centers may not be achievable everywhere. 15

There are several limitations to our current study, namely, its retrospective nature and the inability as in standard Food and Drug Administration approval clinical trials to capture all the relevant preand postoperative parameters to determine risk factors and clinical patterns for complications. The registry is also made up of selfreported data, and although we tried to standardize and collect data in a uniform manner, some are missing and there is some heterogeneity in the types of patients treated. Although the general technique of brachial access and caudally directed parallel stent-grafting was similarly performed, a standardized technique and sequence of steps were not strictly adhered to and the selection criteria for ch-EVAR varied. In addition, the lack of standardization of the technique provides us with a mixture of different aortic endografts and chimney grafts. We believe, though that this may constitute a positive aspect of our study, as the general parallel graft strategy seems to be non-devicedependent, because it works successfully with different types of grafts

and snorkel/chimney stents and in varying experienced operators. Although there is a suggestion that balloon-expandable-covered stents may have a lower type Ia endoleak rate than self-expanding covered stents in our registry, selection bias could account for this issue as more tortuous anatomy often forces the use of self-expanding covered stents. Finally, these are still only midterm results. Although some small series with even longer-term follow-up have raised concerns about the stability of the parallel endograft strategy for complex aneurysms,²³ longer periods of follow-up observation of our patients in this registry are warranted.

CONCLUSIONS

We present the largest collection to date of the snorkel/chimney EVAR strategy for the treatment of juxtarenal and pararenal pathology. Technical success, early mortality, survival, freedom from aneurysm-related death, midterm branch patency and durability, endoleaks, and secondary interventions are all reported and are comparable with published results from series of fenestrated grafts. We, therefore, believe that this parallel graft strategy should be in the armamentarium of surgeon treating complex aortic lesions, because it provides an immediate off-the-shelf solution that is safe, effective, and durable in the midterm. We view this strategy as complementary to fenestrated and branched devices, with numerous advantages and disadvantages depending on the anatomy and presentation of the patient with a complex aneurysm. Although close attention to technical details, device selection, and careful planning to create a sufficient seal zone of at least 20 mm is necessary to achieve good outcomes, the present results indicate that snorkel/chimney EVAR and other parallel graft techniques are a viable treatment method that deserves further study and wider usage.

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Drs Donas and Lee contributed equally to this manuscript and should be considered co-first authors.

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DISCUSSANTS

K.C. Kent (Madison, WI):

This is a great study and a tremendous effort at analyzing the outcomes of a new and innovative technology. Surgeons and all interventionalists are often quick to embrace new technology but less efficient in studying the outcomes in a scientific manner. You are clearly the exception. Although we hail randomized comparative studies as the Holy Grail, registries are often the more practical and expeditious way to accomplish this evaluation. You are to be commended in creating the PERICLES registry, which is a large and comprehensive effort in cataloging the world's experience with snorkel/chimney grafts. The findings, which include 517 patients from 13 centers, are quite positive for a very complex group of patients. Overall, 30-day mortality was 3.7% for elective interventions, and the long-term mortality is as would be expected for this ill group of patients. The complications that one would worry about with this type of intervention include type 1 endoleaks (the number was small and there were only 2 conversions for type 1 leaks) and complications related to the treated vessels: renal failure (about 3% of patients progressed to dialysis), mesenteric ischemia (3 patients total), and ischemic stroke related to the brachial approach (<2%). Thus, the overall outcomes are quite impressive. It is important for the nonvascular surgeons in the audience to realize that there is a competing technology for pararenal and mesenteric aneurysms—grafts that have fenestrations or branches.

The ultimate question is how do the outcomes with snorkel/chimney grafts compare not so much with open surgery but to those of the competing technology.

I have a several questions:

1. For the renal and mesenteric vessels, a variety of conduits were used. Covered balloon-expandable stents covered self-expanding

- stents and noncovered stents. Are there any data to show that 1 approach is more effective than another? What conduit do you
- 2. Are there any data to suggest that 1 type of endograft is more advantageous than another? Is 1 graft more likely to conform around the conduits? Did you perform a comparative analysis with your data?
- 3. You comment in the manuscript that type 1 endoleaks are rare as long as the landing zone is at least 20 mm. Do you have data to suggest that the incidence of endoleak is related to the length of the landing zone?
- 4. All of the centers that were chosen for inclusion have a significant amount of experience with the technique. Is there a learning curve? How much experience did each of these centers have before beginning the initiation of the registry? How is this technology diffused out of the 13 centers in PERICLES?
- 5. And a final question. If you fast-forward a few years when the competing technology fenestrated and branch grafts are Food and Drug Administration-approved and readily available, will snorkel and chimney grafts go away? Is this technique here transiently—to bridge a gap—or will this approach be a viable option over the long term? In other words, how, over the long term, do you think these 2 approaches will stack up against each other?

Great effort. You and your coauthors are to be congratulated.

Response From J.T. Lee:

With regard to which type of conduit for the snorkel graft is better or worse, we did perform subanalysis to look at risk factors for both type Ia endoleak and renal patency.

There was a trend toward iCAST, which is a balloonexpandable covered stent, having improved patency and less type Ia endoleak, but this analysis is limited because of selection bias, because we tend to use iCAST in the straighter renals versus the self-expandable covered stent, the VIABAHN in more tortuous approaches to the branches. I suspect that if you controlled for anatomy and branch angulation, there's probably not a difference.

In terms of the main body endograft type influencing outcomes, it's always been my bias that using a device with suprarenal bare stents to pin the snorkel graft up against the sidewall was favorable. This seemed to come out in this registry because 70% of the worldwide cases tended to be with the Endurant and Zenith device, which both have suprarenal stents. In the univariate analysis of type Ia endoleaks, we actually did note that infrarenal devices didn't perform as well, but that did not stand up in the multivariate analysis.

With regard to endoleak rates and the arbitrary 20 mm of neck, we and other authors have chosen that on the basis of observation. Subanalysis did not find a difference with and without type Ia endoleak (22-mm snorkel length vs 24), but intuitively, a longer seal zone will likely have better long-term durability as with any endovascular strategy.

Learning the procedure is an interesting question, as I think this approach is slightly easier than the fenestrated approach simply due to cannulation of branches without first going through another device/hole. Since the Food and Drug Administration approval of fenestrated devices in the United States, I personally have shifted toward a ratio of 2:1 of fenestrated to the snorkel/chimney technique, reserving this technique for urgent cases, when angulated anatomy makes fenestrated grafts more challenging to line up, and difficult iliac access. Diffusion of the snorkel/chimney technique has already occurred, as many centers are offering this approach as an off-theshelf solution, and this registry confirms the effectiveness of the procedure.

Finally, I do believe that the technique is here to stay and not just a transient bridge toward future technology. The skills obtained during learning snorkel/chimney procedures will translate well to future branched and thoracoabdominal pathology and new devices forthcoming.

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L.D. Britt (Norfolk, VA):

As a nonvascular surgeon, I fully appreciate and accept the epidemic expansion in the endoluminal stents. I would remain in my seat quiet until the last slide that you highlighted, whether the procedure is durable. Do we really have the data as far as long-term durability? As we put these grafts in younger and younger people and people live longer and longer, I'm concerned about durability, which you said that we have obviously met that, and I'm not sure that the data will support that.

Response From J.T. Lee:

Durability, obviously, is in the eye of the beholder. I strongly believe that we have shown midterm up to 2- or 3-year experience in the published literature now with these devices and this approach. I personally have patients now nearly 6 years out with excellent sac exclusion and renal patency. I accept your critique that open surgery has 10-year durability, but it is registries such as this that will hopefully help us provide this type of long-term durability for adequate comparison to other surgical approaches.

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J. Matsumura (Madison, WI):

I have 2 questions.

One, I ask all the fenestrated groups: how many patients died waiting for the device or waiting to be scheduled? If we are treating people with large aneurysms that have annual 15% chance of rupture, and they have to wait 2 months, we may see ruptures. I have had patients waiting who rupture and die. I don't think we include that all the time. Were waiting deaths included?

The second question is how did you pick whom to include in the registry? You may have picked Mario and Frank because you know they publish, but how did you look for possible sites that may not have such good results? Have you kind of skimmed the cream?

Response From J.T. Lee:

I think the waiting time when using the currently approved Food and Drug Administration-approved fenestrated device is one of the advantages of the snorkel/chimney technique because there is no delay. You can do this completely off-the-shelf for urgent cases, and the Zurich group has shown this in its single-center series with ruptured AAAs. Certainly, until we have an off-the-shelf fenestrated device, which is probably 2 or 3 years away, we will see some ruptures while awaiting scheduling or building of a custom device, which often takes 3 to 5 weeks to build and ship.

With regard to putting the centers in the registry together, the current registry authors met at a summit and performed an exhaustive literature search and then contacted all of the sites that had more than just case reports. We are all victims of publication bias, and it is likely that this procedure has been written about by centers with a reasonable outcome with this.

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W. Quinones (Los Angeles, CA):

My question is related to both the literature and our experience, suggesting that the number of snorkels per case has an impact on the type Ia endoleaks. Did you look at that in this registry, and, if so, what is your recommendation? What is the maximum number? Two? Three? Four?

Response From I.T. Lee:

We agree that the more snorkel/chimneys, the increasing risk for gutter type Ia endoleak. Basically, 1 snorkel graft works nearly perfectly every time, with minimal displacement of the main body endograft and a good seal. For us, 2 is probably the maximum that the approach consistently works well. When we've ventured into using 3 or 4 snorkels, you need to consider right-sided arm access, conduit placement in the left arm, increasing stroke issues, and need for longer snorkel grafts. In our series and others, the overall complication rate with 3 and 4 was higher both in the immediate term and in the followup compared to 1 or 2 snorkels.