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Current role of the chimney technique in the treatment of complex abdominal aortic pathologies: A position paper from the PERICLES Registry investigators

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on behalf of the PERICLES Registry Investigators (Fazzini S, Taneva GT, Dalman RL, Tran K, Pecoraro F, Bisdas T, Seifert S, Esche M, Gasparini D, Frigatti P, Adovasio R, Mucelli FP, Damrauer SM, Salenius J, Suominen V, Mangialardi N, Ronchey S, Mestres G, Mosquera NJ)

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Introduction

Historically, chimney/snorkel endovascular aortic repair (Ch-EVAR) emerged as a rescue technique to revascularize and/or preserve inadvertently covered critical branch vessels during infrarenal aortic endografting.[1,2] Next, in its evolutionary path, Ch-EVAR offered a viable treatment option for complex aortic repair, and particularly in situations where fenestrated/branched EVAR was not a therapeutic option due to the lack of availability and/or anatomical constraints.[3] In this context, this technique offered distinct advantages such as off-the-shelf availability, straightforward implantation techniques, and lower resource use-intensity enabling performance by a large number of operators managing patients in many centers around the world.

Summary of the published evidence on Chimney EVAR from the PERICLES registry data (Table 1)

After the initial description of Ch-EVAR as a bailout technique for unintended renal artery coverage, the proliferation and subsequent adoption by operators increasingly occurred over several years.[4] However, a significant limitation to the expanded use of this technique was the lack of a strong scientific-evidence foundation. Notably, this all changed in 2015 with the landmark publication of the clinical results from the **PER**formance of the ch**I**mney technique for the treatment of **C**omplex aortic patho**L**ogi**ES** (PERICLES) registry demonstrating promising outcomes in a variety of complex aneurysm patients,

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including symptomatic and ruptured pathologies, at high- and low-volume medical centers throughout Europe and the USA.[5]

The mean preoperative maximum diameter of the aneurysm sac was more than 70 mm highlighting the need for expedited treatment. The registry involved 13 international centers with a total of 517 patients who had 898 implanted chimney grafts.[5] The reported technical success was 97.1%, with a 30-day mortality of 4.9% and estimated primary patency of 94.1% at a mean follow-up of 17.1 months.[5] Importantly, there were no late aneurysm ruptures.

Device configurations/combinations

Since the procedure involves the use of off-the-shelf devices in an off-label manner, Ch-EVAR practitioners have used several different main-body EVAR devices, as well as covered, uncovered and balloon-expandable or self-expanding nitinol stents. Such a plethora of available options led to the frequent use of heterogeneous combinations which can potentially influence the outcomes. In this context, Scali et al. evaluated various device combinations finding that main-body devices with nitinol stent structure and polyester fabric (e.g. Medtronic Endurant, Santa Rosa, USA) in combination with balloon-expandable covered chimney stents had the highest survival at three years (93%).[6]

Impact of the degree of aortic stent-graft oversizing

Donas et al. found that less than 20% stent graft oversizing was associated with higher risk of type IA endoleak when compared with 30% oversizing (14.3% vs. 2.1%, $p = .02$).[7] Therefore, 30% main aortic graft oversizing was recommended to optimize proximal sealing, regardless of the number of deployed chimney grafts.

Risk of stroke

A noteworthy criticism of Ch-EVAR for treatment of juxatrenal aneurysms (compared with fenestrated graft strategies) is the risk of stroke related to the need to use upper extremity access. A stroke rate of 0–4.0% has been reported by various centers performing Ch-EVAR. To address this concern, in a novel analysis of the PERICLES registry, Bosiers et al. reported a clinically relevant cerebrovascular event rate of 1.9%.[8] Not surprisingly, the use of bilateral upper extremity access was found to be an independent predictor factor associated with a 2.8-fold increased risk for postoperative stroke.[8] This important finding led to the recommendation of using a single-arm access point (e.g. left upper extremity) for Ch-EVAR procedures.

Gender-related outcomes

Another significant contribution from the PERICLES registry was the information gained about sex differences in outcome after complex endovascular aortic repair. Historically, female gender has been reported to be a risk factor for worse postoperative outcomes after both complex endovascular and open aortic repair. Torsello et al. presented a robust gender-stratified analysis for Ch-EVAR patients in the PERICLES registry and found no significant difference in outcomes between men and women with respect to terms of freedom from iliac access re-intervention ($p = .44$), freedom from chimney stent occlusion ($p = .228$), or mortality ($p = .59$).[9] These results further underline the utility of the Ch-EVAR technique due to its versatility to use low profile, flexible abdominal aortic devices in female patients who may harbor hostile iliac access vessels and/or more challenging proximal aortic neck landing zone morphologies.

Use of chimney grafts in type IA endoleaks after EVAR

Indeed, the lessons learned from the PERICLES registry make a compelling illustration about the flexibility of Ch-EVAR especially given its ability for use in both elective and non-elective settings. Furthermore, iterative analyses from the registry brought into sharper focusing on other noteworthy applications of Ch-EVAR such as the remediation of type 1A endoleak after standard infrarenal EVAR.[10] Ronchey et al. evaluated 39 patients from the PERICLES registry who were treated for type IA endoleaks that occurred after a previous infrarenal EVAR.[10] They noted a technical success rate of 89.7%, with a 7.6% risk of persistent type IA endoleak at 30 days and a primary chimney stent patency of 94.3% at 36 months. Thirty-day operative mortality was 2.6%, with a 7.7% all-cause mortality at a mean follow-up of nearly two years.[10] These results suggest that Ch-EVAR could be considered a good treatment option (when compared with open surgical conversion) for this difficult group of patients.

Classification and etiological factors for persistent gutter-related type IA endoleaks

The presumed Achilles heel of Ch-EVAR is the concern regarding gutter endoleaks between the chimney stent and aortic main body stent graft. However, a critically important and often overlooked observation is that the majority of Ch-EVAR gutter endoleaks detected on

completion intraoperative angiography can be expected to resolve spontaneously by the time the first postoperative CTA is performed. This is an important distinction since it is not unusual for presentations, discussions and published editorials to site that Ch-EVAR gutter endoleak rates are exceedingly high. The discussion often aggregates the gutter leaks into a sum total of those detected on completion angiography, the first CTA and even late-onset endoleaks. The PERICLES registry collaborators identified two key factors associated with persistent gutter endoleak.[11] One was the degree of aortic stent-graft oversizing, and the other was related to insufficient length of the new proximal seal zone.[11] The newest findings regard the triple and four/fold chimneys use within the PERICLES registry-treated patients. Although the rates of type IA endoleak (13.4%), chimney graft occlusion (12.7%) and ischemic stroke (2.9%) are higher compared to the prevailing single chimney evidence, the use seems safe with promising midterm results regarding patency and mortality. Table 1 provides a summary of the evidence of Ch-EVAR based upon the published data of the PERICLES registry cohort.

Indications for first-line treatment, as well as anatomical constraints to consider indication for chimney

Table 1. PERICLES Registry findings from first publication in 2015 to latest in 2019.

	Year	Topic	Main findings/conclusion
Donas et al. Annals of Surgery	2015	Overall outcomes in a global registry of Ch-EVAR patients (PERICLES)	517 patients treated with 898 chimney grafts (692 renal arteries, 156 SMA, 50 celiac) with a mean follow-up of 17.1 months. Thirty-day mortality was 4.9%, and three-year estimated survival of 74.9%. Primary patency was 94.1% at latest follow-up. New sealing zone of approximately 20 mm in length and oversizing of the aortic stent graft of 30% represent key findings.
Donas et al. Journal of Endovascular Therapy	2017	Classification of gutter-related endoleaks	Pattern A: Excessive aortic stent-graft Oversizing >30%, enfolding Pattern B: Undersized aortic stent-graft oversizing <30% Pattern C: Inadequate seal zone
Scali et al. Journal of Vascular Surgery	2018	Identifying optimal device combinations for Ch-EVAR	Use of a nitinol/polyester main-body endograft in combination with balloon-expandable covered chimney stents portended greater all-cause survival after Ch-EVAR. Presence of multiple chimney grafts has a 1.8-fold higher risk of stent occlusion.
Bosiers et al. Journal of Vascular Surgery	2018	Prognostic factors of major stroke after Ch-EVAR	Ch-EVAR associated with a 1.9% risk of post-operative transient ischemic attack or stroke. Bilateral upper extremity access (OR 2.79), ruptured settings (OR 5.33) and longer operative times were associated with increased risk of post-operative stroke after Ch-EVAR.
Torsello et al. Vascular	2018	Gender-related differences in Ch-EVAR outcome	At a mean follow-up of 36 months, there was no statistically significant difference in freedom from patency loss (84% vs. 80%, female vs. male, $p = .33$, reintervention ($p = .44$), or 30-day mortality (0% vs. 1.4%, $p = .59$) with respect to gender.
Ronchey et al. Journal of Endovascular Therapy	2018	Evaluation of Ch-EVAR to treat type 1A endoleaks after standard EVAR.	Technical success was achieved in 35 of 39 cases (89.7%), with a 7.6% risk of persistent type 1A endoleak at 30 days. Thirty-day mortality was 2.6%, with a 94.3% primary patency at 36 months.
Donas et al. Vascular	2019	Impact of device oversizing on outcomes after Ch-EVAR	Oversizing of 30% with the Endurant stent graft was associated with significantly lower risk of type 1A endoleaks requiring intervention.
Taneva et al. Journal of Vascular Surgery	2019	Evaluation of Ch-EVAR in suprarenal aortic pathologies	Safe use of triple Ch-EVAR involving the superior mesenteric artery but higher incidence of type IA gutter-related endoleaks compared to single/double chimney cases

Table 2. Indications supporting primary use.

Clinical:
- Symptomatic/contained ruptured JAAA
- Symptomatic/ruptured juxtarenal pathologies such as penetrating ulceration
- Type 1 A endoleak after EVAR

Provider/Center:
- No availability of fenestrated endografts
- No preference and/or center expertise in use of fenestrated endografts due to either high costs or limited experience
- Less costs

Anatomical:
- Aneurysm involvement of only one renal artery and distance to the more proximal uninvolved renal artery is >15mm
- Involvement of 2 renal arteries with orifice at the same level and distance to the SMA is >15mm

Table 3. Considerations limiting primary use.

New sealing neck:
- Distance between lowest renal artery and SMA <15mm
- No native infrarenal neck seal zone
- Severe circumferential calcification
- Narrow (<25mm) or wide (>30mm) neck diameter
- Infra/suprarenal/supra SMA angulation > 75°

Renal artery:
- Diameter <5mm
- Cranial orientation of vessel
- High-grade angulation/tortuosity
- Calcified high-grade stenosis
- Early bifurcation of the renal artery
- Multiple and/or indispensible accessory renal arteries

Proximal Access:
- Shaggy thoracic aorta and/or significant atherosclerotic plaque in the left subclavian artery

Iliac Access:
- Bilateral occlusion
- Bilateral diameter <5 mm
- Bilateral calcified and/or concentric high grade stenosis

EVAR technique are outlined in Tables 2 and 3, respectively.[12]

New evidence and future directions

For the first time, Ch-EVAR has been included in the latest 2019 AAA Treatment Guidelines from the European Society for Vascular Surgery (ESVS) where the technique is recommended in urgent cases and when fenestrated repair is not feasible and/or contra-indicated.[13] The adoption of Ch-EVAR into the ESVS AAA guidelines is an important example that illustrates the significant and increasing role of this technique in the management of complex aortic pathologies. Notably, the recently published guidelines assign the same level of evidence (C) to both Ch-EVAR and fenestrated/branched EVAR.[13] Moreover, the CE mark chEVAR approval in case of the Endurant abdominal stent graft with a balloon expandable covered stent as chimney in having renal indication in 2016 allowed the use of a homogeneous combination of devices optimizing the results. This fact has changed the clinical practice standardizing the technique and providing a more therapeutic profile than a bail out solution. In this context, the on-going multicenter prospective Ch-EVAR trial (ENCHANT: Clinical Trialsgov. Identifier: NCT03320252) might well warrant a designation that features a higher level of evidence (e.g. B) once the trial is completed and patient outcomes are analyzed.[14] Notwithstanding the evolution in evidence supporting the use of Ch-EVAR, there is little doubt that the controversy surrounding Ch-EVAR will continue for the foreseeable future. However, we feel confident that the existing and upcoming PERICLES registry results together with the dissemination of the ENCHANT study results will go a long way to propel Ch-EVAR in its evolution as a viable treatment option within the armamentarium of surgeons managing complex aneurysms. Ultimately, this will result in an improved perception of its utility and efficacy within the vascular community.

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