Lessons From the PERICLES Registry on Complex Aortic Repair

Investigators Konstantinos P. Donas, MD, and Edward Y. Woo, MD, discuss the data from a multicenter European and United States registry of snorkel/chimney technique applications.

Global PERICLES Registry: Rationale, Design, and Data

With Konstantinos P. Donas, MD

What is your impression of the evidence base for application of chimney/parallel graft endovascular aneurysm repair (EVAR) before the PERICLES registry was initiated?

Dr. Donas: The current body of published literature on chimney repair consisted mainly of single-center series reporting on a wide variety of aortic pathologies and several combinations of off-the-shelf devices and chimney grafts in a limited number of patients. As a result, even if the experience was positive, no clear picture of chimney repair outcomes and potential applications was obtained.

How would you summarize the significance of this publication and where it fits into the existing literature?

Dr. Donas: The PERICLES registry, including 517 patients from 13 international centers in the United States and Europe, reflects the current global experience with chimney repair in the largest published series of patients with pararenal pathologies who were treated by total endovascular means. The publication of outcomes in *Annals of Surgery* (with an impact factor of 8.3) highlights the importance of this non–industry-funded project.

How were centers and investigators selected for participation in PERICLES?

Dr. Donas: After a systematic review of the literature, centers that had reported case series with inclusion of more than 10 patients were contacted and asked to participate in the PERICLES registry. This allowed the inclusion of centers with suboptimal experience using the chimney technique in order to reflect the "real-world" clinical practice accurately.

Were there any restrictions regarding types of devices that could be used?

Dr. Donas: All commercially available abdominal endografts and chimney grafts were included in the study.

What were some of the notable trends in device selection in terms of main body grafts?

Dr. Donas: United States–based centers used Zenith stent grafts (Cook Medical) in the majority of the cases (54.2%), whereas the Endurant stent graft (Medtronic, Inc.) was most commonly used at the European centers (62.2%). Overall, Endurant was used in almost 50% of the treated patients and Zenith in 17.3%.

What about selection of branch devices and the decision making with regard to stent type selection?

Dr. Donas: Balloon-expandable covered stents were deployed in 49.2% of the target vessels. Almost 40% were

PERICLES AT A GLANCE

Publication:
Donas KP, Lee JT, Lachat M, Torsello G, Veith FJ; for the PERICLES investigators.
Collected world experience about the performance of the snorkel/chimney endovascular technique in the treatment of complex aortic pathologies: the PERICLES registry. Ann Surg. 2015;62:546-553.

Investigators:
Konstantinos P. Donas, MD, Department of Vascular Surgery, St. Franziskus Hospital Münster
Jason T. Lee, MD, Division of Vascular Surgery, Stanford University Medical Center
Mario Lachat, MD, Division of Vascular Surgery, University Hospital of Zurich
Giovanni Torsello, MD, PhD, Department of Vascular Surgery, St. Franziskus Hospital Münster and Clinic for Vascular and Endovascular Surgery, University of Münster
Frank J. Veith, MD, Division of Vascular Surgery, New York University Medical Center

Ronald L. Dalman, MD, Kenneth Tran, MD, Stanford University Medical Center
Felice Pecoraro, MD, Zurich University Hospital
Theodosios Bisdas, MD, St. Franziskus Hospital
Sven Seifert, MD, Mirko Esche, MD, Clinicum Chemnitz
Daniele Gasparini, MD, Paolo Frigatti, MD, University Hospital S. Maria della Misericordia of Udine
Roberto Adovasio, MD, Fabio Pozzi Mucelli, MD, University Hospital Cattinara
Scott M. Damrauer, MD, Hospital of the University of Pennsylvania
Edward Y. Woo, MD, MedStar Health
Adam Beck, MD, Salvatore Scali, MD, University of Florida Medical Center
David Minion, MD, University of Kentucky Medical Center
Juha Salenius, MD, Velipekka Suominen, MD, University of Tampere
Nicola Mangialardi, MD, Sonia Ronchey, MD; Stefano Fazzini, MD, San Filippo Neri Hospital
Gaspar Mestres, MD, Vincent Riambau, MD, University of Barcelona
Nilo J. Mosquera, MD, Department of Angiology, University of Ourense

Enrollment:
Period: 2008–2014
United States: 119 patients
Europe: 398 patients

898 chimney grafts placed
692 renal, 156 superior mesenteric, and 50 celiac
49.2% balloon-expandable covered stents
39.6% self-expanding covered stents
11.2% balloon-expandable bare-metal stents
No sponsorship from industry

Mean follow-up: 17.1 months
Primary patency: 94%
Secondary patency: 95.3%
Overall survival: 79%

self-expanding stents, and 11.2% were bare-metal stents. There was a trend toward balloon-expandable covered stents having improved patency and fewer type Ia endoleak; however, this analysis is limited because self-expanding chimneys were deployed in more tortuous and challenging anatomies.

Generally, balloon-expandable covered stents have a good fluoroscopic visualization, allowing precise placement. On the other hand, self-expanding devices are flexible and long.

Anatomies and disease in this challenging population can vary considerably, and there is no single standard for chimney construction. To what degree were you able to glean generalizable conclusions across a cohort including aneurysms, ruptures, and penetrating ulcers, and in what areas was this not possible?

Dr. Donas: Use of off-the-shelf devices is beneficial in the urgent setting, making the chimney technique the only totally endovascular therapeutic option in symptomatic or ruptured pararenal cases. The underlying pathologies were degenerative aneurysms in almost 80% of the cases. Based on this, we are able to glean generalizable conclusions. Type IA endoleaks after EVAR and para-anastomotic aneurysms after open aortic aneurysm repair, which can be very challenging, represented almost 8.5% of the treated cases. These are two additional indications for chimney repair that can be successfully treated.

What were the key results in your opinion?

Dr. Donas: In my opinion, there are three key results:

(1) The significant shrinkage of the aneurysm sac. The mean preoperative diameter was 65.9 mm, showing the significant risk for rupture of the treated pathologies, and at a mean imaging follow-up of 17.1 months, this decreased to 61.2% ($P = .001$).

(2) The necessary new neck length after chimney EVAR to achieve durable results has to be about 20 mm. In detail, the new seal length after treatment in our cohort was 21.1 mm compared to the preoperative 4.8-mm neck length.

(3) Type IA endoleak was noted intraoperatively in 7.9% of treated patients. However, after corrective treatment with prolonged kissing-balloon dilatations or additional cuff placement, only 2.9% required invasive treatment. This highlights the fact that in the majority of parallel graft cases, the presence of gutter-related type IA endoleaks is a physiologic, inevitable phenomenon, especially when a sufficient new neck length of 20 mm has been created. Should the endoleak persist, close follow-up and monitoring with frequent imaging are required to exclude significant enlargement of the aneurysm sac.

How did outcomes differ between patients treated using bare-metal and both types of covered stents?

Dr. Donas: The recommended and standard use is a covered stent. Bare-metal stents were mainly placed in cases of an inability to advance the covered stents due to an angulated descending aorta. We did not observe significantly different outcomes between the two subgroups. However, due to the potential risk for retrograde type III endoleak from the aortic branch, we recommend the use of covered stents.

How do the data affect your approach to challenging necks that would otherwise be treated with an infrarenal device?

Dr. Donas: Placement of an infrarenal device was not a considerable option because the mean preoperative neck length of the treated pathologies was 4.8 mm and excludes this. The present global experience highlights the successful use of off-the-shelf devices in a parallel graft strategy. The postoperative degree of sac regression, the primary patency rate of 94.1%, and the relatively low incidence of type IA endoleaks requiring reintervention in more than 500 patients support wider use of the chimney technique. Future studies are ongoing to try to identify the best combinations of aortic and chimney grafts to minimize the gutter areas, and consequently lead to a lower incidence of endoleaks. From my personal point of view, further improvement of the level of evidence regarding the chimney technique will strengthen its complementary role to fenestrated endografting in the endovascular treatment of pararenal aneurysms.

Last but not least, on behalf of the PERICLES investigators, I would like to express my gratitude to Profs. Jason T. Lee, Frank Veith, and Frank Criado of the steering committee of the PERICLES registry for their sustained support and help to conduct and finally publish the present study.

Ass. Prof. Konstantinos P. Donas, MD, PhD, is with the Clinic for Vascular and Endovascular Surgery at St. Franziskus Hospital and Münster University Hospital in Münster, Germany. He has stated that he has received no financial support from industry related to this study. Dr. Donas may be reached at konstantinos.donas@google-mail.com.

Applying PERICLES in a Modern Complex Aortic Practice

With Edward Y. Woo, MD

When you first reviewed the data collected from this group of European and United States aortic experts, were there any specific trends in device selection or patient outcomes that surprised you?

Dr. Woo: Based on my own personal results and the previously published data, I had expected the results to be quite good, so I was not surprised that they were.

One of the benefits of utilizing the parallel graft technique is the ability to use any standard EVAR device. This allows for flexibility in various anatomies, comfort for the interventionist, and reduced profile in instances of difficult access.

In what specific ways did the pooled results match your experiences?

Dr. Woo: The overall results are excellent and similar to what we have been experiencing. Graft patency is > 90% despite the length of some of the snorkel/chimney stents. The rate of type Ia endoleaks is also quite low.

Moreover, most of these patients are quite frail and would never tolerate an open procedure. It is remarkable how quickly these patients will recover, with almost all of them going home rather than to a rehabilitation facility.

What lessons from PERICLES will you apply in your own aortic practice?

Dr. Woo: Mostly, my take-home point is that PERICLES validates this procedure. Many publications have demonstrated excellent results with this technique, but having such a large, multi-institutional study corroborate those findings only further supports it.

In looking at the pioneering period before PERICLES was initiated and what's been learned since, how has the current ability to treat these patients evolved?

Dr. Woo: I think that over this time period, interventionists have become more adept with this technique. In addition, as data continue to demonstrate safe midterm durability, adoption of the technique has increased. Interestingly, industry is focusing R&D on furthering this technology, including development of branch stents and adapting endografts for this technique, etc.

What are the key messages for centers that generally refer their complex cases to those that specialize in these areas?

Dr. Woo: I would recommend continuing those referral patterns. These procedures can be quite challenging and time consuming. Tortuosity of the aorta and branch vessels can exponentially increase the difficulty of the procedure. In addition, increasing the number of parallel grafts also increases the complexity of the case. Having multiple "hands" working together optimizes and shortens the procedure.

If you could pinpoint one capability that would considerably improve your ability to match device with anatomy/disease, what would it be?

Dr. Woo: Aneurysmal disease involving the renovisceral aortic segment can be difficult to manage. One capability, device, or technique isn't enough to simplify the treatment. The interventionist needs to have many skills, "tricks," and techniques, as well as be flexible and adaptable in order to treat these disease processes. Sometimes an expected simple procedure can be difficult and vice versa. ■

Edward Y. Woo, MD, is Director of the MedStar Regional Vascular Program; Chairman of the Department of Vascular Surgery MWHC, MGUH, MSMHC, MSMH, MMMC; and Professor of Surgery at Georgetown University. He has disclosed that he receives speaking and consulting fees from Medtronic, Gore & Associates, and Cook Medical and receives research funding from Medtronic and Gore & Associates. Dr. Woo may be reached at Edward.Y.Woo@medstar.net.