

Valiant Navion Meets Safety and Effectiveness Endpoints

Vascular Disease Management talks with **Ali Azizzadeh, MD**, Professor and Director of the Division of Vascular Surgery, Cedars-Sinai Medical Center and U.S. principal investigator for the Valiant Navion IDE study.



Ali Azizzadeh, MD

New data from the full patient cohort of the pivotal Valiant Navion study were presented by Ali Azizzadeh, MD, Professor and Director of the Division of Vascular Surgery, Cedars-Sinai Medical Center and U.S. principal investigator for the Valiant Navion IDE study. The data presented include 89 subjects with thoracic aortic aneurysms (TAA) or penetrating aortic ulcers (PAU) who were evaluable for the assessment of the protocol specified by the primary

composite endpoint within one year.

The results demonstrated that Valiant Navion thoracic stent (Medtronic) was safe and effective in patients with TAA and PAU. Through one year, there were no access or deployment failures. Based on Kaplan-Meier estimates through one year, freedom from secondary procedures was 94.8%. Furthermore, 97.4% of aneurysms remained stable or decreased in size through one year. Finally, there were no new instances of Type 1a endoleaks beyond 30 days.

Can you describe this trial design?

The Valiant Evo IDE Trial is a prospective, multi-center, non-randomized, single-arm trial.

The trial was designed to assess the safety and effectiveness of the new Valiant Navion Thoracic Stent Graft System in patients with a descending thoracic aortic aneurysm (DTAA) who were candidates for endovascular repair.

The clinical performance of the Valiant Navion Thoracic Stent Graft was evaluated in a total of 100 patients with a hypothesis-based, 30-day premarket composite safety and effectiveness endpoint.

The proposed primary composite safety and effectiveness endpoint is based on the proportion of patients who experienced: (a) access and/or deployment failures; and/or (b) major device effect (MDE) within 30 days post index procedure (MDEs include the occurrence of any of the following: device-related secondary procedures, device-related mortality, conversion to open surgery, thoracic aortic aneurysm rupture).

What was the patient population/demographics of the study?

Patients who were appropriate candidates for endovascular repair of the DTAA and who met the inclusion/exclusion criteria.

Of the 100 patients enrolled, 40% were female, and the median age was 72 years (range 49 to 89 years) (**Figure 1**). Fifty-three

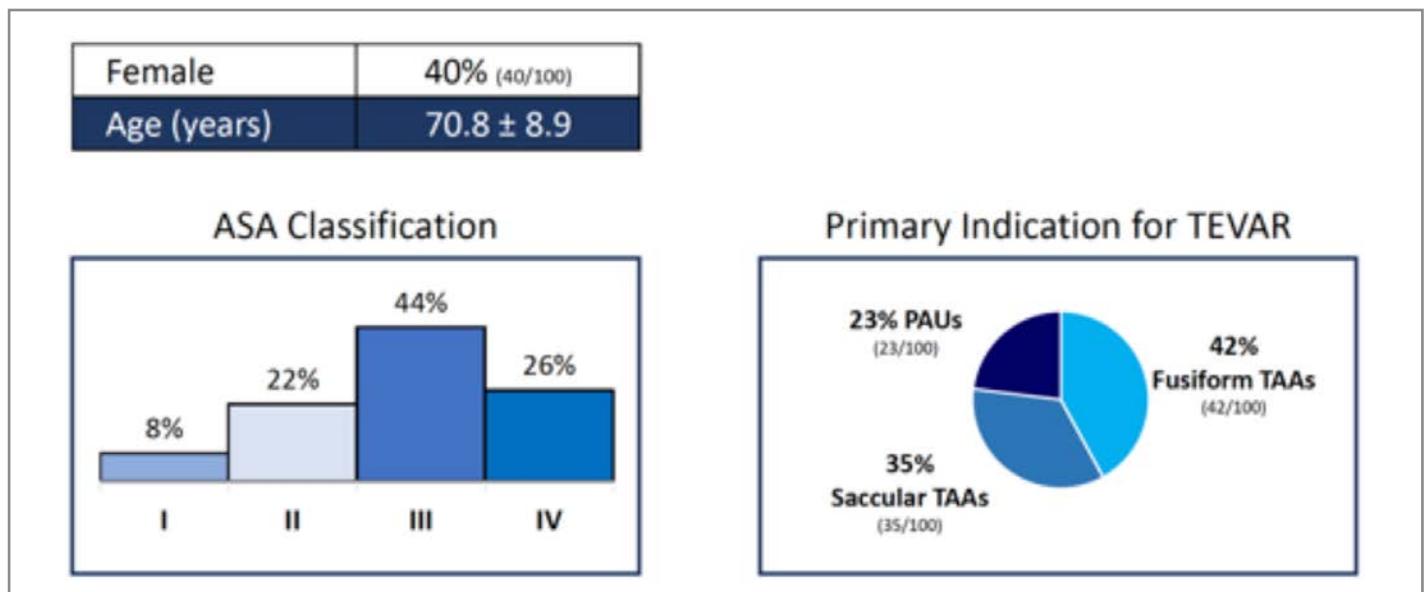


Figure 1. Demographics and primary indication.

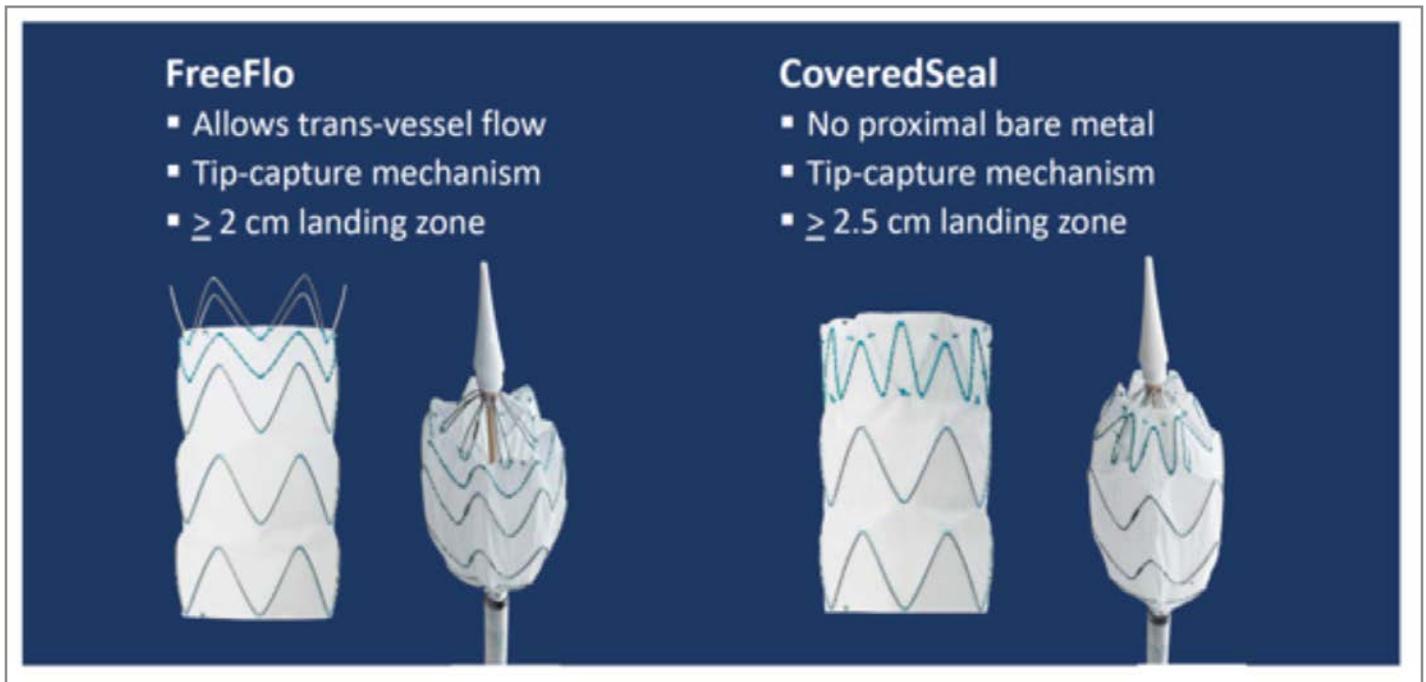


Figure 2. Valiant Navion (Medtronic) proximal device configuration options.

patients were enrolled from 18 U.S. sites, and 47 were enrolled from 15 sites outside the United States. Racial data was only collected among the U.S. cohort, with 79.2% (42/53) of the U.S. patients reported as white.

The most prevalent medical history diagnoses at baseline included hypertension in 87% (87/100) of patients and hyperlipidemia in 69.7% (69/99) of patients. Of note, tobacco use in the last 10 years was prevalent in 50.5% (50/99) of patients, coronary artery disease in 33% (33/100), and diabetes in 22% (22/100).

What distinguishes the Valiant Navion?

The Valiant Navion has a lower crossing profile that allows access to the aorta through smaller and more tortuous vessels (**Figure 2**). This profile expands thoracic endovascular aortic repair applicability to a wider range of patients.

In addition, this device is now available in a CoveredSeal configuration, without any bare metal at the leading edge, which is ideal for patients with fragile aortas, such as aortic dissection.

The device is also more conformable and has an expanded size matrix, including a broader diameter range, extended lengths, and enhanced tapering.

What were the results of the study?

The Valiant Evo U.S. and International Trials met the primary composite safety and effectiveness endpoint, defined as access/deployment failures and MDEs within 30 days, with an event rate

of 2.3% (2/87) (**Figure 3**). This event rate was lower than the performance goal of 16% and was statistically significant ($P < 0.001$). From 0 to 30 days, freedom from MDE was reported in 98% of 100 subjects. Two patients experienced 4 events (2 device-related secondary procedures, 1 descending thoracic aortic aneurysm [DTAA] rupture, and 1 device-related mortality). No access or deployment failures of the Valiant Evo Thoracic Stent Graft System occurred in the trial.

How long were patients followed?

All patients included were followed under the investigational protocol beyond the 30-day primary endpoint out to 60 months post-implantation, with yearly follow-up visits following the index procedure.

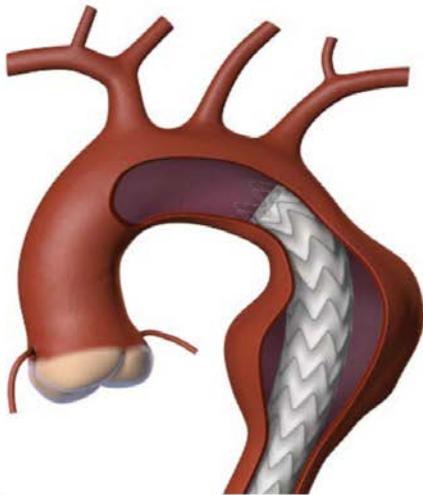
Were there any adverse events?

Secondary safety endpoints at 12 months included aneurysm-related mortality (3.3%; 3/90), device-related secondary procedures (3.4%; 3/89), and thoracic aortic aneurysm rupture (1.1%; 1/88).

What is the main conclusion from this study?

The composite safety and effectiveness primary objectives were achieved in the trial. The global cohort met the objective performance goals set for the primary endpoint, access/deployment

Procedural 1 year Results – Core Lab Reported



FF Secondary Procedures within 365 Days	94.8%
Migration within 365 days	0%
Endoleaks at 1 year follow-up visit	
Type Ia	0.0% (0/75)
Type Ib	4.0% (3/75)
Type II	2.7% (2/75)
Type III/IV/V	0.0% (0/75)
Aneurysm Sac Dynamics	
Stable or Decreasing	97.4% (74/76)
Increasing	2.6% (2/76)

Patients with secondary procedures: 1 surgical, 4 endovascular

Encouraging Durability Signals

Figure 3. Procedural 1-year results from the Valiant Navion trial.

failures, and for MDEs within 30 and 365 days of the index procedure. Based on the clinical data presented, it can be concluded that the Valiant Navion Thoracic Stent Graft System is safe and effective for the treatment of DTAA in patients who are candidates for endovascular repair.

What do you anticipate in terms of timelines and results from future studies?

All patients from the global Valiant Evo trial will be followed yearly for 5 years. The sponsor is also in the process of initiating an aortic dissection post-market registry. The registry will enroll at least 200 patients diagnosed with a dissection of the thoracic aorta at approximately 45 global sites. Data from this registry will fill the evidence gap as a result of the pivotal trial only enrolling aneurysm patients. The first patient is expected to be enrolled spring 2020. The registry will collect data until 3 years follow-up. ■

Disclosure: The Valiant Navion IDE study was funded by Medtronic. Dr Azizzadeh reports he received research funding and honoraria from and consults for Medtronic and W.L. Gore and Associates.

Address for correspondence: Dr Azizzadeh is Professor & Director of the Division of Vascular Surgery at Cedars-Sinai Medical Center, 127 S. San Vicente Blvd. Suite A3600, Los Angeles, CA 90048. Phone: 310-423-0246.