Gender analysis of the pivotal results of the Medtronic Talent Thoracic Stent Graft System (VALOR) trial

Benjamin M. Jackson, MD,[a] Edward Y. Woo, MD,[a] Joseph E. Bavaria, MD,[b] and **Ronald M. Fairman, MD,[a]** *Philadelphia, Pa*

Purpose: **This study evaluated the differences between male and female patients undergoing thoracic endovascular aneurysm repair (TEVAR) in a pivotal Food and Drug Administration (FDA)-approved trial.**

Methods: **The Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) study was a prospective, nonrandomized, multicenter, pivotal trial conducted in the United States. Patients were enrolled between December 2003 and June 2005. Follow-up was conducted at 30 and 365 days.**

Results: **VALOR enrolled 115 men (58.9%; 69.3 ± 11.7 years old), and 80 women (41.1%; 71.6 ± 10.1 years old). Iliac conduits were used more often in women, who had smaller diameter external iliac arteries, than in men (38.8% vs 8.8%, $P < .001$). Women required more blood transfusions and had a longer hospital length of stay. At 30 days, more major adverse events occurred in women than in men (52.5% vs 33.0%, $P = .008$), with more vascular access-related and respiratory complications. No gender-based differences were seen in all-cause mortality or in aneurysm-related death. The composite end point of 365-day "successful aneurysm treatment," defined as no aneurysm growth >5 mm at the 365-day follow-up visit compared with the 30-day follow-up visit and absence of any type I endoleak requiring a secondary procedure, favored women over men (98.2% vs 82.4%, $P = .004$).**

Conclusions: **TEVAR with the Talent device provided similar rates of 365-day mortality and morbidity for men and women. Although female patients had higher rates of periprocedural complications, they also more often had successful aneurysm treatment at the 1-year follow-up. (J Vasc Surg 2011;54:358-63.)**

In series of endovascular repair (EVAR) of abdominal aortic aneurysms (AAAs), the ratio of men to women undergoing repair is between 4:1 and 5:1.[1] In contrast, in series of patients undergoing thoracic endovascular repair (TEVAR) for thoracic aortic aneurysms (TAA), the ratio of men to women is between 1:1 and 3:1.[2,3] Therefore, as the U.S. Food and Drug Administration (FDA) evaluates and approves thoracic stent graft devices, it is important to evaluate their safety and efficacy in female patients specifically. Because women have smaller iliac and femoral arteries, and smaller normal-diameter aortas, device sizing and delivery system size may contribute to differing outcomes between the genders.

The Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) study was a prospective, nonrandomized, multicenter, pivotal trial conducted at 38 sites to evaluate the 30-day and 365-day results of endovascular treatment using the Medtronic Vascular Talent Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, Calif) in patients with TAAs who were considered candidates for open surgical repair with low to moderate surgical risk.[4] The results were compared with retrospective open thoracic aneurysm repairs on 189 patients at three centers of excellence. The trial enrolled 195 patients. Compared with patients undergoing open surgery, patients undergoing TEVAR benefitted with respect to acute procedural outcomes, 30-day major adverse events (MAEs; 41% vs 84.4%, $P < .001$), perioperative mortality (2% vs 8%, $P < .01$), and 365-day aneurysm-related mortality (3.1% vs 11.6%, $P < .002$).[4]

This report addresses differences in the procedural results and primary outcome measures between the 115 male and 80 female VALOR patients to assess whether gender affects the safety and efficacy of TEVAR or the performance of the Talent device; as such, new data and conclusions are presented.

METHODS

Patient selection in the VALOR trial. The VALOR trial was a prospective, nonrandomized, multicenter clinical study conducted in the United States to evaluate the safety and efficacy of the Medtronic Vascular Talent Thoracic Stent Graft System in the treatment of aneurysmal disease of the descending thoracic aorta. Enrollment occurred between December 2003 and June 2005 at 38 institutions. Enrolled patients were diagnosed with TAA and were considered candidates for open surgical repair with low to

From the Divisions of Vascular Surgery and Endovascular Therapy[a] and Cardiothoracic Surgery,[b] Department of Surgery, University of Pennsylvania.

Competition of interest: none.

Corresponding author: Benjamin M. Jackson, Assistant Professor of Surgery, Division of Vascular Surgery, Hospital of the University of Pennsylvania, 4th Flr Silverstein Pavilion, Philadelphia, PA 19104 (e-mail: benjamin.jackson@uphs.upenn.edu).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a competition of interest.

0741-5214/$36.00

doi:10.1016/j.jvs.2010.12.064

moderate risk according to the modified criteria of the Society for Vascular Surgery and the American Association for Vascular Surgery.[5] Anatomic and medical inclusion and exclusion criteria were identical with the original report of the pivotal trial.[4] The VALOR trial was approved by the FDA and site Institutional Review Boards. Patients signed an informed consent before participation in the investigational study.

Technique and device description. During VALOR trial enrollment, the Talent device consisted of a modular preloaded stent graft and the CoilTrac delivery system (Medtronic Vascular). The implanted endoprosthetic portion of the Talent system is composed of a polyester graft fabric sewn to a self-expanding nickel-titanium wire frame. Catalog and custom stent graft configurations were available for the VALOR trial. Stent graft oversizing of 2 to 4 mm relative to the native aortic diameter (measured as adventitia to adventitia) was recommended to provide the necessary outward radial force to maintain stent graft apposition against the aortic wall. The VALOR trial required a minimum overlap of 30 mm for multiple stent grafts. The Reliant balloon catheter (Medtronic) was used at the discretion of the physician to expand the stent graft against the aortic wall and in overlap regions. Adjunctive surgical techniques, including iliac artery conduits, spinal drains, and left subclavian artery revascularization, were left to the surgeons' discretion.

Standard follow-up evaluations were performed at 30, 180, and 365 days. Follow-up visits included a computed tomography (CT) scan, chest radiograph, and physical examination. All clinical data were reported by the investigative center on case report forms and monitored by Medtronic, the sponsor of the study. A clinical events committee adjudicated MAEs for their relationship to the device or the procedure. M2S (West Lebanon, NH) served as the imaging core laboratory and provided data evaluation of all imaging studies, ensuring third-party assessment of graft effectiveness.

Subsequent to FDA review of the VALOR trial, the Talent Thoracic Stent Graft System was approved in June 2008.

End points and definitions. The primary safety end point of the VALOR trial was all-cause mortality at 365 days. The primary effectiveness end point, successful aneurysm treatment, was a composite consisting of two outcomes: (1) no aneurysm growth >5 mm at the 365-day follow-up visit compared with the 30-day follow-up visit; and (2) absence of any type I endoleak requiring a secondary procedure performed before, during, or as a result of the evaluation at the 365-day follow-up visit.

An MAE was defined as death due to the procedure, any death within ≤30 days of the procedure, respiratory complications, renal insufficiency or failure, a cardiac event, a neurologic event, aneurysm rupture, bowel ischemia, major bleeding, or vascular complications. Endoleaks were defined according to the well-established type I to IV nomenclature.[6] Migration was defined as >10 mm proximal or distal movement of the stent graft relative to fixed anatomic landmarks. Aneurysm expansion was defined as a >5-mm increase in diameter between the 1-month and 12-month follow-up visits. Aneurysm-related death was defined as any death ≤30 days from the initial implantation or occurring as a consequence of an aneurysm rupture, a conversion to open repair, or any other secondary endovascular procedure associated with the aneurysm that was treated by the Talent device, as evidenced by CT scan, angiography, or direct observation at surgery or autopsy.

Table I. Aneurysm anatomy and symptoms

Variable	*Male (n = 115) % (No)*	*Female (n = 80) % (No)*	P[a]
Fusiform TAA	54.8 (63)	61.3 (49)	.381
Saccular/penetrating ulcer TAA	38.3 (44)	32.5 (26)	.450
Fusiform + saccular/penetrating ulcer TAA	7.0 (8)	6.3 (5)	>.99
Aneurysm symptoms	26.1 (30)	26.3 (21)	>.99
Pain	13.0 (15)	20.0 (16)	.233
Nausea	1.7 (2)	1.3 (1)	>.99
Chest pain	13.0 (15)	13.8 (11)	>.99
Hoarseness	2.6 (3)	3.8 (3)	.691
Abdominal pain	1.7 (2)	5.0 (4)	.230
Other	6.1 (7)	6.3 (5)	>.99

TAA, Thoracic aortic aneurysm.
[a]Fisher exact test.

Statistical analysis. For categoric variables, the number in each category and the percentage of known values are provided; unless otherwise indicated, *P* values were calculated using χ^2 tests. For continuous variables, the mean and standard deviation are provided; for some parameters the median values are also provided. Unless otherwise indicated, *t* tests were used to assess gender-dependence of continuous variables, and Wilcoxon rank sum tests were used for nonparametric continuous variables. Kaplan-Meier analysis was used to describe freedom from adverse events over time. Values of $P \leq .05$ were considered significant.

RESULTS

Preoperative characteristics. The 195 patients enrolled in the VALOR trial consisted of 115 men (58.9%) and 80 women (41.1%). Baseline medical history for the entire cohort has been reported previously.[4] With respect to pre-existing conditions and medical history, there were no statistically significant differences between male and female cohorts. Similarly, there were no differences between male and female patients in baseline anatomic characteristics or symptomatic status (Table I). Aneurysm length and maximal diameter did not differ between male and female patients, but proximal and distal neck diameters and bilateral external iliac diameters were all significantly smaller in female patients than in male patients (Table II).

Procedure and hospital course. Deployment of the study device at the intended site was successful in 194 patients (99.5%); the exception was a patient who did not receive a device because of access failure. Notably, that patient was a man. Iliac conduits were required more frequently in women than men (38.8% vs 8.8%, $P < .001$). Women more frequently required a blood transfusion and

Table II. Preoperative core laboratory vessel dimensions

Variable	*Male (n = 109) Mean ± SD, mm*	*Female (n = 78) Mean ± SD, mm*	P[a]
Proximal neck diameter	32.4 ± 4.9	29.5 ± 4.4	<.001
Maximum aneurysm diameter	55.7 ± 11.7	55.2 ± 11.6	.533
Distal neck diameter	30.5 ± 5.3	28.6 ± 4.4	.014
Aneurysm length	123.5 ± 73.7	118.4 ± 71.5	.590
	(n = 71)	*(n = 53)*	
Minimum diameter			
Right external iliac[a]	7.1 ± 1.4	5.7 ± 1.3	<.001
Left external iliac[a]	7.3 ± 1.4	5.7 ± 1.3	<.001

[a]Wilcoxon rank sum test.

had a greater mean volume of blood loss than men. Procedural variables are summarized in Table III. Although intensive care unit length of stay was not significantly different for women (59.8 ± 153.4 hours) than men (37.8 ± 75.8 hours, $P = .515$), the overall hospital length of stay was significantly longer for women (9.0 ± 16.2 days vs 4.7 ± 5.8 days, $P < .001$).

With regard to devices used, a clear trend was noted toward implantation in men of larger-diameter grafts and toward implantation in women of the smallest grafts. Fifteen 46-mm proximal main devices were used in the trial, of which 14 were implanted in men; meanwhile, of the four 22-mm and 24-mm proximal main devices used, three were implanted in women. Nevertheless, no significant difference was detected with respect to proximal graft oversizing (Table III).

Safety and efficacy. There was no difference between male and female patients with respect to all-cause mortality at 30 days or 365 days (Fig, Table IV), nor was there any difference with respect to aneurysm-related mortality at 365 days by log-rank ($P = .71$) or Fisher exact ($P = .84$) tests. The primary effectiveness end point, successful aneurysm treatment at 365 days, was significantly higher in women than in men (98.2% vs 82.4%, $P = .004$): women were less likely than men to have a change in maximum aneurysm diameter of >5 mm between 30 and 365 days (1.8% vs 13.7%, $P = .023$).

At 30 days, significantly fewer MAEs occurred in men than in women (33.0% vs 52.5%, $P = .008$). Accounting for this difference, vascular complications (13.9% vs 36.3%, $P < .001$) and respiratory complications (7.8% vs 21.3%, $P = .009$) were less common in men than in women. Of note, no correlation was detected between vascular complication incidence and vessel size. Other MAEs are summarized in Table V.

DISCUSSION

These results from the pivotal VALOR trial of the Talent thoracic stent graft indicate that TAA repair in women is at least as effective as in men. In the 365-day composite measure "successful aneurysm treatment," female patients fared better than male patients (98.2% vs 82.4%). From the current data, it is unclear whether this will result in improved aneurysm-free survival in the long term; 1-year survival in the current data demonstrates no difference in overall mortality. Although one might guess that the higher "successful aneurysm treatment" rate in women might be due to smaller necks—and hence more likely proximal seal—the percentage of oversizing was similar between genders.

Complications were more commonly seen in women in the trial, however. Women had more frequent MAEs and had greater blood loss and more frequent transfusion requirements. Given that the difference in MAEs was largely due to more frequent vascular complications and—in particular—more frequent "vessel disruption," it seems logical that much of the increased blood loss, complication risk, and transfusion requirement resulted from the smaller access vessels in women. The lack of correlation detected between vascular complication incidence and vessel size was likely due to lack of power in the study to detect the correlation and to the confounding element of conduit utilization.

Other published experiences with the Talent device have not always demonstrated such high rates of access injury.[7] However, as a prospective pivotal trial, the reporting in this study is verifiable, and the results highlight the fact that access-related complications or failure are a real risk in TEVAR. Of note, the delivery system used for the Talent endograft in the VALOR trial was a previous generation system. More recent delivery systems from various manufacturers, including Medtronic, have incorporated hydrophilic sheaths, among other improvements.

The observed higher rate of respiratory complications in women might be due to any number of factors, including differences in resuscitation (crystalloid and transfusion products) and differences in predisposing degrees of chronic lung disease. This difference in respiratory complications is constituted largely in a higher rate of pneumonia in women than men.

A disadvantage of all currently available thoracic stent grafts is their large-diameter delivery systems. Depending on device diameter, the delivery system catheter outside diameter ranges from 22F to 25F for Talent grafts. The more treacherous vascular access in women may be mitigated by frequent use of adjunctive access procedures, such as conduit creation. In the current trial, conduits were used three times more frequently in women than in men. Other studies have reported a similar overall rate of use of conduits.[8]

A prior study conducted to determine the anatomic barriers to TEVAR for TAA evaluated 126 patients (73 men and 53 women) with isolated TAA. Of this total, 33 (26%) were rejected for TEVAR on anatomic grounds.[9] The rejected patients were generally older (>70 years) and had aneurysms of significant size (6.4 ± 1.4 cm), and they were excluded for more than one criterion. However, rejection was not significantly different by gender (16 men vs 17 women, $P = .22$). There were also no gender-based

Table III. Details of procedures

Procedural details	*Male (n = 114)*[a]	*Female (n = 80)*[a]	P
LSA revascularization before initial procedure	5.3 (6)	5.0 (4)	>.99[b]
Iliac conduit	8.8 (10)	38.8 (31)	<.001[b]
Study devices implanted per subject	2.8 ± 1.4	2.6 ± 1.2	.350[c]
Subjects requiring blood transfusion	15.8 (18)	32.5 (26)	.009[b]
Blood loss during procedure, mL	269 ± 407	516 ± 611	<.001[d]
Duration of implant procedure, min	140.7 ± 72.2	173.3 ± 77.7	<.001[d]
Volume of contrast used, mL	163.9 ± 91.7	137.4 ± 79.7	.028[d]
Proximal oversizing			.125[b]
<10%	14.5 (16/110)	15.4 (12/78)	
10%-20%	40.9 (45/110)	26.9 (21/78)	
>20%	44.5 (49/110)	57.7 (45/78)	

LSA, Left subclavian artery.
Categoric data are presented as percentage (number) and continuous data as mean ± standard deviation.
[a]Unless otherwise noted.
[b]Fisher exact test.
[c]χ^2 test.
[d]Wilcoxon rank sum test.

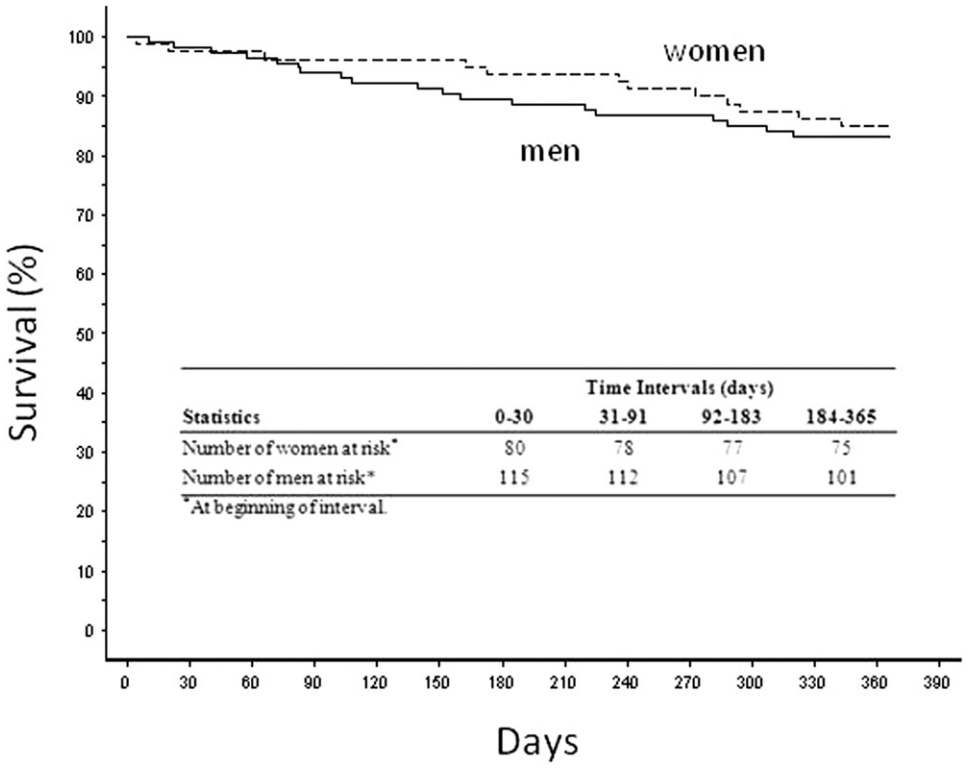

Fig. Kaplan-Meier plot of freedom from all-cause mortality at 365 days for male and female participants in the VALOR trial.

differences in the proportion of aneurysms with hostile proximal necks, hostile distal necks, or both. More of the rejected female patients had difficult access anatomy, but the difference was not significant.

This gender analysis of the results of the pivotal VALOR trial represents the most extensive examination to date of differences between male and female patients in response to TEVAR. Several studies have suggested that male patients with AAA are younger and possibly have better outcomes than female patients.[10,11] In a large cohort study of 12,917 AAA patients treated with open or endovascular repair, gender was not associated with differences in mortality rates, but aneurysm-related death was more common in female than in male patients.[12] The investiga-

Table IV. Safety and efficacy

Variable	*Male (n = 115)[a] % (No.)*	*Female (n = 80)[a] % (No.)*	P[b]
All-cause mortality			
≤30 days	1.7 (2)	2.5 (2)	>.99
At 365 days	16.8 (19/113)	15.2 (12/79)	.843
Aneurysm-related death ≤365 days	2.7 (3/113)	3.8 (3/79)	.691
Paralysis at 30 days	0.9 (1/115)	2.5 (2)	.569
Paraparesis at 30 days	6.1 (7)	8.8 (7)	.576
Successful aneurysm treatment at 365 days	82.4 (61/74)	98.2 (55/56)	.004
Change in aneurysm diameter >5 mm between 30 and 365 days	13.7 (10/73)	1.8 (1/56)	.023
Secondary endovascular endoleak repair	6.4 (7/109)	5.2 (4/77)	>.99
Conversion to open surgical repair	0.9 (1/112)	0 (0)	>.99
Aneurysm rupture	0 (0/112)	1.3 (1)	.417
Migration of stent graft >10 mm	3.4 (2/58)	4.4 (2/45)	>.99
Endoleaks	15.9 (11/69)	7.4 (4/54)	.176
Type I	4.3 (3/69)	5.6 (3/54)	>.99
Type II	7.2 (5/69)	1.9 (1/54)	.228
Type III	0 (0/69)	0 (0/54)	—
Indeterminate	4.3 (3/69)	0 (0/54)	—

[a]Unless noted otherwise.
[b]Fisher exact test.

Table V. Major adverse events at 30 days

Event	*Male (n = 115) % (No.)*	*Female (n = 80) % (No.)*	P[a]
Respiratory complications	7.8 (9)	21.3 (17)	.009
Pneumonia	5.2 (6)	15.0 (12)	.025
Pulmonary embolism	0.9 (1)	0 (0)	>.99
Respiratory failure	3.5 (4)	10.0 (8)	.074
Renal insufficiency or failure	7.0 (8)	5.0 (4)	.764
Myocardial infarction	1.7 (2)	1.3 (1)	>.99
Neurologic complications	8.7 (10)	16.3 (13)	.119
Stroke	1.7 (2)	6.3 (5)	.125
Paraplegia	0.9 (1)	2.5 (2)	.569
Paraparesis	6.1 (7)	8.8 (7)	.576
Bowel ischemia	0.9 (1)	1.3 (1)	>.99
Vascular complications	13.9 (16)	36.3 (29)	<.001
Expanding hematoma at access site	2.6 (3)	0 (0)	.270
Pseudoaneurysm at access site	0.9 (1)	3.8 (3)	.307
Retroperitoneal bleed	1.7 (2)	3.8 (3)	.402
Arterial occlusion	0.9 (1)	3.8 (3)	.307
Vessel rupture/dissection	7.0 (8)	5.0 (4)	.764
Vessel disruption	1.7 (2)	16.3 (13)	<.001
Embolism	2.6 (3)	8.8 (7)	.095
Reoperation for limb ischemia	0.9 (1)	1.3 (1)	>.99
Total major adverse events	33.0 (38)	52.5 (42)	.008

[a]Fisher exact test.

tors speculated that this result might actually be due to untreated TAA, noting that in women, TAA might be more equally distributed than AAA.

Gender differences—with regard to anatomic features and suitability for endografting at least—have been examined for AAAs. A study by Velazquez et al[13] demonstrated that smaller iliac arteries and shorter, more angulated proximal necks might limit applicability of EVAR in women compared with men. The current study similarly demonstrates smaller external iliac arteries and smaller proximal and distal neck diameter, but no evidence of shorter proximal necks in TAAs in women relative to men. Meanwhile, some investigators have demonstrated more frequent access-related complications in women than in men undergoing EVAR.[14,15]

Although the Talent TEVAR experience summarized here does not include an examination of gender-based differences in exclusion from TAA repair, other studies have addressed this issue for both TEVAR and EVAR. In particular, Moise et al[16] demonstrated that women were more likely than men to be excluded from EVAR because of anatomic features. However, the same group did not find any female predilection toward anatomic rejection for TEVAR during pivotal stent graft trials performed at a single institution.[9] Clearly, design of future-generation thoracic stent grafts will require attention to the requirements inherent in treating women.

An advantage of the Talent device is the wide range of diameters: from 22 to 46 mm for treatment of aortic diameters from 18 to 42 mm. TEVAR in younger patients—for example, those with aortic transection—and in women may be facilitated with the smaller devices. Supporting this supposition, female patients in the current study had smaller diameter proximal and distal necks, and in three women (compared with only one man) 22-mm or 24-mm proximal main grafts were implanted.

CONCLUSIONS

The gender analysis of the pivotal VALOR trial suggests that women with aneurysms of the descending thoracic aorta may be treated as successfully as men with the Talent Thoracic Stent Graft System. Female patients undergoing TEVAR with this device, however, did have higher rates of periprocedural complications and 30-day MAEs, especially vascular compli-

cations, and the surgeon must remain cognizant of both delivery system size and access vessel diameter.

AUTHOR CONTRIBUTIONS

Conception and design: BJ, RF
Analysis and interpretation: BJ, EW, JB, RF
Data collection: BJ, RF
Writing the article: BJ, RF
Critical revision of the article: BJ, EW, JB, RF
Final approval of the article: BJ, EW, JB, RF
Statistical analysis: BJ
Obtained funding: Not applicable
Overall responsibility: BJ

REFERENCES

1. Mani K, Björck M, Lundkvist J, Wanhainen A. Improved long-term survival after abdominal aortic aneurysm Repair. Circulation 2009;120: 201-11.
2. Orandi BJ, Dimick JB, Deeb GB, Patel HJ, Upchurch GR Jr. A population-based analysis of endovascular versus open thoracic aortic aneurysm repair. J Vasc Surg 2009;49:1112-6.
3. Bavaria JE, Appoo JJ, Makaroun MS, Verter J, Yu ZF, Mitchell RS. Endovascular stent grafting versus open surgical repair of descending thoracic aortic aneurysms in low-risk patients: a multicenter comparative trial. J Thorac Cardiovasc Surg 2007;133:369-77.
4. Fairman RM, Criado F, Farber M, Kwolek C, Mehta M, White R, et al. Pivotal results of the Medtronic Vascular Talent Thoracic Stent Graft System: the VALOR Trial. J Vasc Surg 2008;48:546-54.
5. Chaikof EL, Fillinger MF, Matsumura JS, Rutherford RB, White GH, Blankensteijn JD, et al. Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. J Vasc Surg 2002;35:1061-6.
6. White GH, Yu W, May J, Chaufour X, Stephen MS. Endoleak as a complication of endoluminal grafting of abdominal aortic aneurysms: classification, incidence, diagnosis, and management. J Endovasc Surg 1997;4:152-68.
7. Fattori R, Nienaber CA, Rousseau H, Beregi J, Heijmen R, Grabenwoger M, et al. Results of endovascular repair of the thoracic aorta with the Talent Thoracic stent graft: the Talent Thoracic Retrospective Registry. J Thorac Cardiovasc Surg 2006;132:332-9.
8. Greenberg R, Resch T, Nyman U, Lindh M, Brunkwall J, Brunkwall P, et al. Endovascular repair of descending thoracic aortic aneurysms: an early experience with intermediate-term follow-up. J Vasc Surg 2000;31:147-56.
9. Jackson BM, Carpenter JP, Fairman RM, Moser GW, Pochettino A, Woo EY, et al. Anatomic exclusion from endovascular repair of thoracic aortic aneurysm. J Vasc Surg 2007;45:662-6.
10. Pleumeekers HJ, Hoes AW, van der Does E, van Urk H, Hofman A, de Jong PT, et al. Aneurysms of the abdominal aorta in older adults. The Rotterdam Study. Am J Epidemiol 1995;142:1291-9.
11. Sukhija R, Aronow WS, Yalamanchili K, Sinha N, Babu S. Prevalence of coronary artery disease, lower extremity peripheral arterial disease, and cerebrovascular disease in 110 men with an abdominal aortic aneurysm. Am J Cardiol 2004;94:1358-9.
12. Hultgren R, Granath F, Swedenborg J. Different disease profiles for women and men with abdominal aortic aneurysms. Eur J Vasc Endovasc Surg 2007;33:556-60.
13. Velazquez OC, Larson RA, Baum RA, Carpenter JP, Golden MA, Mitchell ME, et al. Gender-related differences in infrarenal aortic aneurysm morphologic features: issues relevant to Ancure and Talent endografts. J Vasc Surg 2001;33(2 Suppl):S77-84.
14. Wolf YG, Arko FR, Hill BB, Olcott C IV, Harris EJ Jr, Fogarty TJ, et al. Gender differences in endovascular abdominal aortic aneurysm repair with the AneuRx stent graft. J Vasc Surg 2002;35:882-6.
15. Simons P, van Overhagen H, Nawijn A, Bruijninckx B, Knippenberg B. Endovascular aneurysm repair with a bifurcated endovascular graft at a primary referral center: influence of experience, age, gender, and aneurysm size on suitability. J Vasc Surg 2003;38:758-61.
16. Moise MA, Woo EY, Velazquez OC, Fairman RM, Golden MA, Mitchell ME, et al. Barriers to endovascular aortic aneurysm repair: past experience and implications for future device development. Vasc Endovasc Surg 2006;40:197-203.

Submitted May 1, 2010; accepted Dec 18, 2010.

Additional material for this article may be found online at www.jvascsurg.org.

Appendix (online only)

In addition to the authors of this article, the following principal investigators and trial sites participated in the pivotal VALOR trial: Mark Farber, MD, University of North Carolina, Chapel Hill, NC; Christopher Kwolek, MD, Massachusetts General Hospital, Boston, Mass; Alan Matsumoto, MD, University of Virginia, Charlottesville, Va; Edward H. Garrett, MD, Cardiovascular Surgery Clinic, Memphis, Tenn; Gregorio Sicard, MD, Washington University School of Medicine, St. Louis, Mo; Manish Mehta, MD, Albany Medical College, Albany, NY; Rodney White, MD, Harbor UCLA Medical Center, Los Angeles, Calif; Alan Lumsden, MD, Baylor College of Medicine, Houston, Tex; W. Anthony Lee, MD, University of Florida, Gainesville, Fla; J. Michael Tuchek, MD, Loyola University Medical Center, Maywood, Ill; Frank Criado, MD, Union Memorial Hospital, Baltimore, Md; Michael Dake, MD, University of Virginia, Charlottesville, Va; David Williams, MD, University of Michigan, Ann Arbor, Mich; Zvonimir Krajcer, MD, St Luke's Episcopal Hospital-Houston, Houston, Tex; Robert Rhee, MD, Shadyside Hospital-UPMC, Pittsburgh, Pa; Sean Lyden, MD, Cleveland Clinic Foundation-Ohio, Cleveland, Ohio; Jim Swischuk, MD, St Francis Hospital, Peoria, Ill; Paul Bove, MD, William Beaumont Hospital, Royal Oak, Mich; Kim Hodgson, MD, Memorial Medical Center, Springfield, Ill; Robert Allen, MD, Physician's Regional Medical Center, Naples, Fla; Phillip Allmendinger, MD, Hartford Hospital, Hartford, Conn; Mark Bates, MD, Charleston Area Medical Center, Charleston, WV; Daniel Benckart, MD, Allegheny General Hospital, Pittsburg, Pa; Tom Bower, MD, Mayo Clinic-Rochester, Rochester, Minn; Mark Eskandari, MD, Northwestern Memorial Hospital, Chicago, Ill; Neal Cayne, MD, NYU Vascular Associates, New York, NY; Peter Faries, MD, New York Presbyterian Cornell University, New York, NY; Mark Fillinger, MD, Dartmouth-Hitchcock Medical Center, Lebanon, NH; Marc Glickman, MD, Sentara Norfolk General, Vascular, and Transplant Specialists, Norfolk, Va; Matthew Jung, MD, Surgical Care Associates, Louisville, Ky; Barry Katzen, MD, Baptist Hospital of Miami, Miami, Fla; Lowell Satler, MD, Washington Hospital Center, Washington, DC; Richard McCann, MD, Duke University Medical Center, Durham, NC; Takao Ohki, MD, Montefiore Medical Center, Bronx, NY; Venkatesh Ramaiah, MD, Arizona Heart Institute, Phoenix, Ariz; Timothy Roush, MD, Carolinas Medical Center, Charlotte, NC; Cary Stowe, MD, Florida Hospital, Orlando, Fla; Christopher Zarins, MD, Stanford University, Stanford, Calif.