Gender-related differences in infrarenal aortic aneurysm morphologic features: Issues relevant to Ancure and Talent endografts

Omaida C. Velazquez, MD, Robert A. Larson, MD, Richard A. Baum, MD, Jeffery P. Carpenter, MD, Michael A. Golden, MD, Marc E. Mitchell, MD, Ann Pyeron, RN, Clyde F. Barker, MD, and **Ronald M. Fairman, MD,** *Philadelphia, Pa*

Purpose: **The purpose of this study was to determine whether gender-related anatomic variables may reduce applicability of aortic endografting in women.**

Methods: **Data on all patients evaluated at our institution for endovascular repair of their abdominal aortic aneurysm were collected prospectively. Ancure (Endovascular Technologies (EVT)/Guidant Corporation, Menlo Park, Calif) and Talent (World Medical/Medtronic Corporation, Sunrise, Fla) endografts were used. Preoperative imaging included contrast-enhanced computed tomography and arteriography or magnetic resonance angiography.**

Results: **One hundred forty-one patients were evaluated (April 1998–December 1999), 19 women (13.5%) and 122 men (86.5%). Unsuitable anatomy resulted in rejection of 63.2% of the women versus only 33.6% of the men (P = .026). Maximum aneurysm diameter in women and men were similar (women, 56.94 ± 8.23 mm; men, 59.29 ± 13.22 mm; P = .5). The incidence of iliac artery tortuosity was similar across gender (women, 36.8%; men, 54.9%; P = .2). The narrowest diameter of the larger external iliac artery in women was significantly smaller (7.29 ± 2.37 mm) than in men (8.62 ± 2.07 mm; P = .02). The proximal neck length was significantly shorter in women (10.79 ± 12.5 mm) than in men (20.47 ± 19.5 mm; P = .02). The proximal neck width was significantly wider in women (30.5 ± 2.4 mm) than in men (27.5 ± 2.5 mm; P = .013). Proximal neck angulation (>60 degrees) was seen in a significantly higher proportion of women (21%) than men (3.3%; P = .012). Of the patients accepted for endografting, a significantly higher proportion of women required an iliofemoral conduit for access (women, 28.6%; men, 1.2%; P = .016).**

Conclusion: **Gender-related differences in infrarenal aortic aneurysm morphologic features may preclude widespread applicability of aortic endografting in women, as seen by our experience with the Ancure and Talent devices. In addition to a significantly reduced iliac artery size, women are more likely to have a shorter, more dilated, more angulated proximal aortic neck. (J Vasc Surg 2001;33:S77-84.)**

Direct repair of abdominal aortic aneurysms (AAAs) with the standard open surgical techniques, although time-honored and proved as effective, has significant morbidity and mortality rates. In particular, women have a higher morbidity and mortality rate than men when undergoing emergency or elective open AAA repairs.[1,2] With the advent of transluminal technology, the endovascular approach has gained increased acceptance by both surgeons and patients. The ever-rising popularity for this method can be easily understood, given its perceived minimal invasiveness[3] and the accumulating evidence that indicates decreased procedure morbidity and mortality rates.[4-7] However, not all patients who could benefit from the endovascular approach are candidates for this less invasive method. The need for continued improvement in the existing endovascular technology should be emphasized. Patient selection, most strikingly restricted by aneurysm anatomy, continues to be of paramount importance for the achievement of rupture-free long-term success.[8] As the increasing number of clinical studies fuel and guide the impetus for perfecting the endovascular technology in the treatment of AAA, little data exist about the risk factors, which increase the likelihood of anatomy unsuitability for the endovascular approach. Specifically, there are limited data on the suitability of this technology for women, even for Food and Drug Administration (FDA)–approved devices.[9] At the core of the concern about the unsuitability of aneurysm anatomy are the problems with adverse intraoperative events,[10-13] primary and delayed anchoring site endoleaks,[14] and delayed aneurysm rupture despite successful endografting.[15-17] For reasons that are not well understood, the female gender has been identified as a risk factor for primary endoleaks[12] after aortic endografting. The aim of this study was to determine whether women are at increased risk of not being considered for endovascular repair of AAA because of aneurysm

From the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine.

Competition of interest: nil.

Reprint requests: Omaida C. Velazquez, MD, Department of Surgery, 4 Silverstein Pavilion, 3400 Spruce St, Hospital of the University of Pennsylvania, Philadelphia, PA 19104.

0741-5214/2001/$35.00 + 0 **24/0/111921**
doi:10.1067/mva.2001.111921

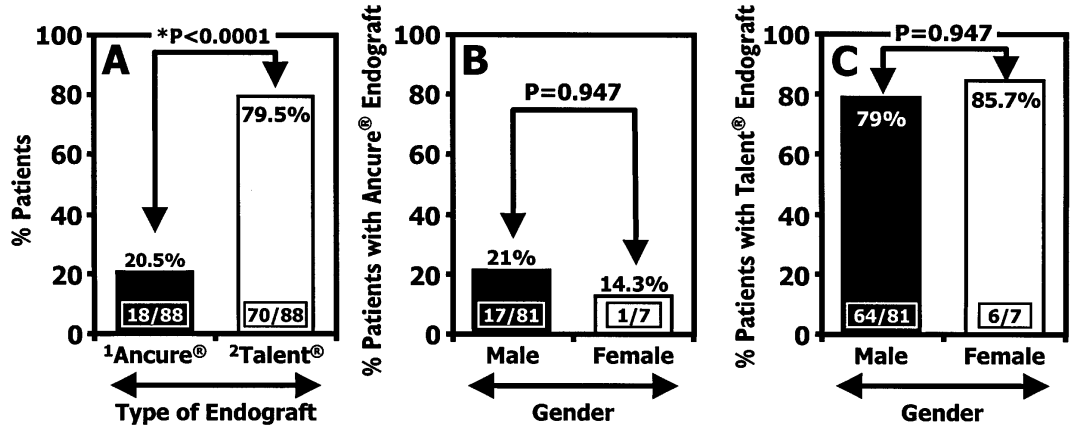

Fig 1. Analysis of **(A)** the endografts used overall, **(B)** Ancure endograft distribution by gender, **(C)** Talent endograft distribution by gender from April 1998 to December 1999.

Table I. Rejection criteria for the endovascular technique related to anatomy and aneurysm morphologic variables when either the Ancure or the Talent device was used

Infrarenal aortic neck length: <6 mm (Talent); <15 mm (Ancure)
Infrarenal aortic neck diameter: >30 mm (Talent); >26 mm (Ancure)
Circumferential thrombus at renal arteries
Severe calcification at anchoring sites
Severe angulation (>60 degrees) at proximal anchoring site
External iliac artery size: <7.5 mm + not a candidate for iliofemoral conduit
Bilateral common iliac artery or hypogastric arteries aneurysm
Common iliac artery: >18 mm (Talent); >13.4 mm (Ancure)

anatomy features that prohibit successful aortic endografting and that may be more prevalent in the female patients.

This series represents our experience with two commercially available aortic endoprostheses used for the endovascular treatment of infrarenal AAAs. One of the endoprostheses is FDA approved. The second endoprosthesis is in phase 2 clinical trials. The two endoprostheses have completely different design philosophies in terms of their body design, type of delivery system, type of reinforcement of the graft, and type of fixation. The major strength of this study relates to the novel report of specific aneurysm morphologic features that are more complex and more frequently seen in female patients, which potentially lead to decreased suitability for endovascular repair with either an Ancure (Endovascular Technologies [EVT]/Guidant Corporation, Menlo Park, Calif) or a Talent (World Medical/Medtronic Corporation, Sunrise, Fla) endoprosthesis.

METHODS

Patients. From April 1998 to December 1999, all patients with infrarenal AAA who came to our center for evaluation were informed about the options of the "open" versus endovascular repair. Many patients came to our medical center (self-referred or referred by another physician), specifically to determine whether they were candidates for endovascular repair. All patients were given the option of participating in ongoing phase II multicenter clinical trials, which involved the evaluation of the Ancure and the Talent endografts. All patients who wished to be evaluated for the endovascular approach from April 1998 to December 1999 are included in this study. As part of the evaluation, all patients underwent preoperative imaging by thin-cut (3 mm) contrast computed tomography (CT scan), digital subtraction angiography with marker catheter, and/or gadolinium-enhanced magnetic resonance angiography (MRA) to determine anatomic suitability. The minimum imaging workup, in patients with normal renal function, included the contrast CT scan. An angiogram was not performed if the CT scan met the rejection criteria. In patients with renal insufficiency, a noncontrast CT scan and an MRA were obtained as the minimum imaging workup. These patients with renal insufficiency would not undergo a contrast arteriogram (unless it had already been obtained at an outside institution, before their evaluation at our medical center).

Methods of anatomic assessments. The CT scan was used for diameter measurements. Parallax error was avoided by obtaining measurements from the three-dimensional reconstruction of the cross-sectional CT data and software-generated measurements with the use of free-hand cursor capability. For the proximal neck diameter, the cursor was placed from outer wall edge to outer wall edge on the aorta, caudad to the most inferior renal artery. Similarly, measurements for the distal landing zones and the external iliac arteries were obtained by placing the cursor from outer wall edge to outer wall edge on the target artery and avoiding parallax by the use of three-dimensional reconstructed CT data. Longitudinal measurements were obtained from digital subtraction angiography with marker catheters. The larger of the two external iliac arter-

Table II. Comorbidity of patients

Comorbidity	*No. of men* (%)*	*No. of women† (%)*	P *value*
Hypertension	45 (36.9)	7 (36.8)	NS
Diabetes mellitus	12 (9.8)	2 (10.5)	NS
Cardiac disease (overall)	60 (49.2)	8 (42.1)	NS
Angina	32 (26.2)	2 (10.5)	NS
Prior myocardial infarction	24 (19.7)	2 (10.5)	NS
Congestive heart failure	10 (8.2)	1 (5.3)	NS
Prior coronary artery bypass	28 (23)	3 (15.8)	NS
Prior coronary angioplasty	7 (5.7)	1 (5.3)	NS
Chronic obstructive pulmonary disease	24 (19.7)	5 (26.3)	NS
Smoking history (>20 pack/y)	30 (24.6)	4 (21.1)	NS
Chronic renal insufficiency (>1.5 mg/dL)	26 (21.3)	3 (15.8)	NS
Renal failure (dialysis)	4 (3.3)	0 (0)	NS
Peripheral vascular disease	6 (4.9)	0 (0)	NS
Total (all evaluated patients)	122 (86.5)	19 (13.5)	.013

NS, Not significant.
*Age, 74.52 ± 8.15 years; *P* = NS.
†Age, 77.58 ± 6.33; *P* = NS.

Table III. Major adverse events and early endoleaks

	No. of men (%)	*No. of women (%)*	P *value*
Intraoperative major adverse events (overall)	4 (4.9)	1(14)	NS
Conversion to open surgical repair (unplanned)	1(1.2)	1(14)	NS
Iliac artery rupture	2 (2.5)	0 (0)	NS
Unable to access/aborted case	1(1.2)	0 (0)	NS
Endoleaks at 30 days (overall)	15 (18.5)	2 (28.6)	NS
Anchoring site endoleaks	2 (2.5)	1 (14)	NS
Collateral endoleaks	13 (16)	1 (14)	NS
Total no. of patients who underwent endovascular repair	81 (66.4)	7 (36.8)	.026

NS, Not significant.

ies was considered the access vessel. Along the full length of the external iliac artery chosen for access, the limiting factor was considered to be its narrowest segment. The diameter of this narrowest segment from the larger external iliac artery was the variable monitored as an index of accessibility with the endovascular devices. Measurements of angulation and tortuosity were obtained from the CT scan three-dimensional reconstruction data, the angiograms, and the MRA (when available). Severe angulation at the proximal neck was defined as more than 60 degrees for the angle between the aneurysm and the infrarenal aortic neck for desired infrarenal fixation or the angle between the infrarenal neck and the suprarenal aorta for desired suprarenal fixation. Moderate and severe tortuosity were subjective ratings entered prospectively per case and were based on the assessment of the extent of coiling of the external iliac arteries. All MRA measurements were software generated with a free-hand cursor and followed the same guidelines for the CT scan measurements. These data were confirmed twice in an independent fashion (once by a radiologist and once by a vascular surgeon). Because of the use of computerized tools and specific guidelines for measurements, there was a high degree of concordance between the radiologist's and the vascular surgeon's measurements.

Iliofemoral conduits. An iliofemoral conduit (8-mm polyester graft) to bypass the external iliac artery was used only when the external iliac arteries were unsuitable for access. In all cases, this was due to a smaller than needed diameter for the larger external iliac artery. An iliofemoral conduit was contraindicated in the presence of bilateral common iliac artery aneurysms or when the common iliac arteries were too small to provide access.

When the anatomy of the aneurysm and/or native vasculature precluded endovascular repair with either of the two devices under study (Table I), patients were then evaluated for open surgical repair at our center or at the original referring center. Patients were also informed of other investigational endovascular devices and trials at other centers and given the option for reevaluation. Patients were informed of the necessary radiographic follow-up and the relatively limited data accumulated on the long-term efficacy for the endovascular approach. When the anatomy of the aneurysm was amenable to the endovascular approach, patients were enrolled; written informed consent had been obtained, in accordance with the guidelines and approved by our Institution Review Board and the FDA agency. Informed consent included an understanding and acceptance by the patient of the necessary long-term follow-up period. Data were collected prospectively and analyzed retrospectively.

Table IV. Perioperative morbidity and deaths

	No. of men (%)	*No. of women (%)*	P *value*
Major perioperative morbidity (overall)	2 (2.5)	1 (14)	NS
Pneumonia	0 (0)	1 (14)	NS
Myocardial infarction	1 (1.2)	0 (0)	NS
Stroke	0 (0)	0 (0)	NS
Renal failure (new-onset dialysis)	1 (1.2)	0 (0)	NS
Inpatient perioperative deaths	3 (3.7)	1 (14)	NS
Total no. of patients who underwent endovascular repair	81 (66.4)	7 (36.8)	.026

NS, Not significant.

Aortic endografts. The endoprostheses under investigation included two types of polyester-covered endovascular systems: (1) the Ancure stent-graft composed of a polyester graft (tube, bifurcated, and aorto–uni-iliac systems) with self-expanding elgiloy hooks at proximal and distal ends for anchoring and (2) the Talent stent-graft, a modular system in which the individual components are assembled within the patient to form the desired graft (bifurcated and aorto–uni-iliac systems). Each Talent graft-module consists of a polyester fabric supported by a Z-shaped nitinol framework. The uncovered proximal portion of the stent-graft can be designed with wide openings of "bare spring" that allow suprarenal fixation of the graft. The fixation depends on radial force.

Table I summarizes the aneurysm anatomy features that excluded patients from becoming a candidate for either one of these two devices. The Ancure trial was initiated first at our center; shortly thereafter, the Talent trial was initiated. Although for most of the study period, both the Ancure and Talent devices were available, as a standard (arbitrary but consistent) part of our endovascular protocols, all patients were considered for an Ancure device first. If the patient's aneurysm morphologic features were not amenable to exclusion with the Ancure device, the patient was then considered for a Talent device, which has a broader range of anatomic suitability (Table I). The distance between the distal end of the common iliac artery dilatation and the hypogastric artery that precluded endovascular grafting for patients with bilateral common iliac artery aneurysms was 20 mm. The maximum neck diameter with the Talent system was limited to 30 mm because of the need for a 20% oversize of the device above the actual diameter of the infrarenal aortic neck width. The Talent device depends on radial force for proximal and distal fixation. As a result, the recommended specifications for the device include at least a 20% oversize at the proximal fixation site and a 10% oversize at the distal iliac artery fixation site. Therefore, although the device can be customized to a maximum diameter of 36 mm, this would allow the treatment of a 30 mm infrarenal aortic neck diameter.

Postoperative follow-up period. Patients underwent follow-up contrast CT scans with 3-mm cuts at 1 week, 1 month, 6 months, and 1 year of follow-up. The endoleaks were detected by intravenous contrast 3-mm cut CT scans and further confirmed (plus their cause studied) by angiogram. Many patients had the diagnosis of an endoleak made before discharge or shortly thereafter, at the 1 week follow-up CT scan. For patients whose endoleak was persistent at the repeat 1-month follow-up CT scan, an arteriogram was performed to confirm the endoleak and investigate its cause.

Endograft designs. Graft designs were based on aneurysm morphologic features and extent. Two thirds of our patients had a bifurcated graft design, and one third of our patients had an aorto–uni-iliac design. Only one patient had a tube graft design. Suprarenal fixation was used in 68 patients in this series (all those patients were treated with a Talent endovascular graft because the Ancure fixation is always infrarenal). The distance between the distal end of the common iliac artery dilatation and the hypogastric artery that precluded endovascular grafting for patients with bilateral common iliac artery aneurysms was 20 mm.

Statistical analysis. All patients who were evaluated for the endovascular approach were divided into two groups, men and women. Measurements are expressed as mean ± SD. Gender differences in the aneurysm morphologic measurements, native vasculature measurements, age, preexisting comorbidity, and early perioperative outcome data were evaluated by the Student *t* test, the chi-squared test, and the Fisher exact test (for small *n* values), respectively. All calculations were performed with Primer of Biostatistics for Windows 95 version 4.0 (part no. 864181-0; Stanton A. Glantz, McGraw-Hill, Inc, Health Professions Division, New York, NY).

RESULTS

From April 1998 to December 1999, 141 patients (19 women [13.5%] and 122 men [86.5%]; $P = .013$) were evaluated for endovascular repair of infrarenal AAA at our center. The male to female ratio for all patients was approximately 6.4:1. Patients were excluded from repair by the endovascular approach on the basis of the rejection criteria outlined in Table I. Exclusion of patients was due to short aneurysm neck (17 patients; 32%), wide aneurysm

neck (11 patients; 20%), circumferential thrombus at the renal arteries (nine patients; 16%), severe calcification at the anchoring sites (five patients; 9.4%), severe neck angulation (three patients; 5.7%), inadequate access because of small iliac arteries (19 patients; 35.8%), bilateral hypogastric artery aneurysms (11 patients; 20.8%), and the presence of bilateral common iliac artery aneurysms closer than 20 mm to the hypogastric arteries (12 patients; 22.6%). Patients who were rejected for repair of the aneurysm by the endovascular method had an average of 1.7 exclusion criteria (range, 1-3; mode 2). The analysis of the gender subsets within each of these eight categories of anatomy and aneurysm morphologic features was limited by too small a number of patients within each of the subgroups. However, in total, a disproportionate number of women were rejected as a result of unfavorable native anatomy and aneurysm morphologic features ($P < .026$). Age and preexisting comorbidity were similar across genders (Table II). There were no patients who declined consent for evaluation as candidates for the endovascular repair, which included the outlined radiographic studies and follow-up. Unsuitable anatomy was the only reason that resulted in rejection from an endovascular aneurysm repair. Rejection because of unsuitable anatomy occurred in 63.2% of the women versus 33.6% of the men ($P = .026$).

An analysis of all patients by gender indicated that the maximum aneurysm diameter in women and men were similar (women, 56.94 ± 8.23 mm; men, 59.29 ± 13.22 mm; $P = .5$). Also, the incidence of iliac artery tortuosity was similar across gender (women, 36.8%; men, 54.9%; $P = .2$). In contrast, the diameter of the narrowest segment on the larger external iliac artery (the access vessel of choice) was significantly smaller in women (7.29 ± 2.37 mm) than in men (8.62 ± 2.07 mm; $P = .02$). Also, the proximal neck length was significantly shorter in women (10.79 ± 12.5 mm) than in men (20.47 ± 19.5 mm; $P = .02$), and the infrarenal aortic neck diameter was significantly wider in women (30.5 ± 2.4 mm) than in men (27.5 ± 2.5 mm; $P = .013$). Proximal neck angulation (>60 degrees) was seen in a significantly higher proportion of women (21%) than men (3.3%; $P = .012$).

Eighty-eight patients were found to be good candidates (accepted) for aortic endografting. There were no significant differences in the types of endograft used for women and men (Fig 1). However, the Talent endograft was used much more frequently than the Ancure endograft in both men and women (Fig 1).

Of the patients accepted for aortic endografting, a significantly higher proportion of women required an iliofemoral conduit for access (women, 28.6%; men, 1.2%; $P = .016$). There were no significant differences across gender in the major adverse intraoperative events, early or late endoleak rates, major perioperative morbidity rates, or inpatient perioperative mortality rates (Tables III and IV). There have been no late aneurysm ruptures after endografting, with a mean follow-up of 18 months (range, 6-24 months).

In this group of patients, we have encountered only two late endoleaks. Both endoleaks occurred in male patients, and both were from collateral circulation through lumbar arteries (type II). One of these two patients had also experienced an early endoleak that was related to a patent inferior mesenteric artery. This had been treated at the 1-month follow-up by selective coil-embolization of the inferior mesenteric artery. The patient subsequently underwent CT scan, which documented no evidence of endoleak. However, the 1-year follow-up CT scan showed a new endoleak that, on further study (by selective angiogram), was found to be the result of lumbar artery flow. The second patient did not have an early endoleak on the 1-month and 6-month follow-up CT scans. However, this patient experienced a new late endoleak that was, on further investigation, found to be the result of flow through lumbar arteries.

Major intraoperative adverse events are listed in Table III, and major morbidity and mortality rates are listed in Table IV. The inpatient mortality rate listed in Table IV indicates the 1 month plus the inpatient mortality rate and is the result of the major postoperative medical complications listed.

DISCUSSION

This study has shown that based on anatomic exclusion criteria; women are more likely than men to be rejected for endovascular AAA repair. We have shown that specific unfavorable aneurysm morphologic features (short, wide, tortuous infrarenal aortic neck) are more commonly observed in women than men who undergo evaluation for endovascular AAA treatment. Also, the native iliac arteries are significantly narrower in women, which leads to the increased use of surgically placed iliofemoral conduits to gain access to the aneurysm during aortic endografting. To our knowledge, this is the first report that identifies gender-related differences in infrarenal AAA morphologic features that negatively affect female patients in suitability for the endovascular technology.

The cause for the observed gender differences in our study is unknown. It is possible that, for hormonal or genetic reasons, the female gender has more of a propensity for complex aortic aneurysm morphologic features. Data from previous large studies on open AAA repair have documented unexplained gender differences in AAA treatment and outcomes, with increased negative outcomes in women relative to men.[1,2] Across all age groups, women are less likely than men to undergo emergency or elective aortic reconstruction, and when they do, they have a 1.45 times greater risk of dying than men.[1,2] Age and preexisting comorbidity are only weakly implicated as potential

influences on aneurysm extent and on treatment outcome.[1,2,18-20] A study relating complicated aneurysm anatomy to gender, in particular related to the infrarenal aortic neck, has never been reported. The relevance of such anatomic features is obvious when discussing the endovascular approach but may also play an important role in open surgical repair because the infrarenal neck is the preferred site for the proximal clamp. Therefore, if the proximal control during open AAA repair is complicated by more complex anatomy, it may likely have a negative influence on outcome.

In our series, age and comorbidity were similar across gender and are therefore unlikely to account for the observed gender differences in the frequency of complex aneurysm morphologic features. It is possible that women have more advanced aneurysms at evaluation than do men, relative to the size of their native vessels. [2,21] Although the maximum aneurysm diameter in our patients was similar across gender, the size of the iliac arteries was significantly smaller in women, which suggests a more advanced pathologic condition relative to the size of the native vasculature.

Slightly fewer women than would be predicted were evaluated during our study period. The male:female incidence of hospitalizations for ruptured and unruptured AAA was reported to be 5:1 in a study from the United States that included 11,512 women and 29,846 men.[1] A large population-based study from Australia reported the male:female incidence of AAA as 5.8:1. In our series, the male-to-female ratio in all evaluated patients was 6.4:1. This may be the result of under diagnosing, late diagnosing, or late referral for surgical treatment in women with AAA.[1] It has been noted that women with intact AAAs of similar size as men are one half as likely to undergo surgery for the aneurysm.[1] Alternatively, we may be evaluating fewer women for endovascular repair as a result of a potential prestudy bias, at which time fewer women are referred because of obvious unfavorable anatomy identified by the referring physicians. In view of our observations in this study, the latter potential bias could be possible. It is also possible that the referral pattern to our tertiary care medical center may have introduced bias by preselecting patients with more difficult anatomies and older patients with more significant comorbidities. However, it is difficult to determine if such a bias has occurred or how it could result in a higher proportion of female patients with complex aneurysm morphologic features, relative to the male patients.

We used two different endografts: Ancure and Talent. These devices differ substantially in design and exemplify the main important design options: the unibody design with anchoring-site–support/hook attachment/infrarenal fixation (Ancure) versus the modular design with full-body–support/radial force attachment/suprarenal bare-spring fixation (Talent). These design concepts may directly impact the profile of the delivery systems, the limits on length and width for effective fixation sites, and potential long-term durability with aneurysm remodeling. The Talent device allowed us to treat a significantly higher number of patients (both men and women). This indicates that most of the patients who we treated (men and women alike) had complex aneurysm morphologic features, which excluded them from the Ancure protocol. It might be expected that the Talent device would have been used in a preponderance of women because it is applicable in a wider range of aneurysm morphologic features. In fact, six of seven women were treated with a Talent, and only one woman was treated with an Ancure device. However, on evaluation of all the patients who underwent endovascular repair, an Ancure device (and similarly a Talent device) was just as likely to be used in women as in men. That is, the male:female distribution was similar for each of the two endografts. Although the number of patients within each subgroup remains too small for definitive conclusions, these data indicate that neither device is better suited for the aneurysm morphologic features observed in most of the female patients in this series.

As can be seen in Table I, in general, the Talent device can be applied to a wider range of native anatomy and aneurysm morphologic features than the Ancure device (ie, shorter infrarenal aortic neck lengths, wider infrarenal aortic diameters, and wider common iliac arteries as the distal landing zone). As a result, six of the seven women required the use of a Talent device and would not have been good candidates for an Ancure device. Similarly, 64 of the 81 male patients had aneurysm morphologic features that allowed successful treatment with the Talent device, but not with the Ancure device. Therefore, a significantly higher proportion of patients in our study population was treated with a Talent device rather than an Ancure device (Fig 1). However, the male-to-female distribution (after accounting for the significantly higher number of male patients evaluated compared with female patients) was similar for both endografts (Fig 4; $P = .947$). We interpret these findings as an indication that, although the Talent device broadens the range of aneurysm morphologic features that can be treated with the endovascular approach, it continues to have problems with capturing most of the female patients (as shown by the data presented in this work).

On carefully reviewing our findings, it is likely fair to conclude that most aortic endograft devices already FDA-approved and currently under investigation would not be widely applicable to an external iliac diameter of 7.29 mm, an infrarenal aortic neck length of 10.7 mm, an infrarenal aortic neck width of 30.5 mm, and a severe (>60-degree)

proximal neck angulation. However, these are, in fact, the measurements as they pertain to our group of female patients. Moreover, up to one third of the male patients also exhibited similarly adverse anatomy. Because most patients who underwent evaluation were male, the absolute number of male patients rejected for the endovascular approach because of unsuitable anatomy was 3.4 times that of the number of rejected female patients. Therefore, although the incidence of complex anatomy observed was much higher in women and the relative impact of improved devices may be greater in the female patients, an even larger number of male patients could potentially be treated with further advancements in design concepts and technology.

Because only seven women underwent endovascular repair, there is a significant risk for type II error, as shown in Tables III and IV, given that the subgroup analysis includes a very small number of patients. For this reason, the absolute numbers given may be more informative than the calculated percentages shown. Tables III and IV summarize the experience observed in this series and are not intended to be interpreted as the definitive assessment on outcome analysis based on gender. Outcome analysis based on gender for endovascular repair of AAAs remains an important topic that requires future study in a larger number of patients.

This work was designed to determine whether gender-related differences in the morphologic features of infrarenal aortic aneurysms may lead to a reduced applicability of endografting in women as seen by suitability to undergo endovascular repair with either an Ancure or a Talent endograft. Several other endovascular systems are available. Other endovascular systems may differ in their suitability for various aneurysm morphologic features. Each of these devices may be associated with other features that may make them more or less suitable to the high incidence of complex aneurysm morphologic features that we see associated with the female gender. Specifically, a higher incidence of shorter, more dilated and angulated infrarenal aortic aneurysm neck and very narrow external iliac arteries in association with the dilated aortic neck require larger, higher profile endografts. The strength of this work is to report, for the first time, these important observations on gender-related differences. These data may be of benefit in stimulating discussion for design improvements.

This series represents our experience on the first 141 consecutively evaluated patients from which 88 patients underwent endovascular repair. A major intraoperative adverse event rate of 5 of 88 (5.7%) was observed. Our experience is similar to that reported by several other major centers.[4-12] The major adverse intraoperative events were as follows. One male and one female patient were converted to open surgical repair. The female patient was converted to open surgical repair, electively, after an Ancure device could not be properly placed. The most important difficulties in this case were access problems (external iliac artery tortuosity and calcification) that led to significant distortion (crimping and twisting) of the delivery system. The male patient was converted to open surgical repair, emergently, as a result of rupture of the aneurysm sac, during devise (bifurcated Talent graft) implantation. On retrospective analysis of potential causes for this latter complication, it is likely that excessive force was transmitted to the aneurysm sac during delivery (in this case also, very tortuous and calcified iliac arteries resulted in difficulties with access). The two patients who sustained external iliac artery rupture (and two conversions to open surgical repair and the aborted case) happened in the early part of our experience (the first 25 cases). The iliac ruptures were related to overly aggressive ballooning at the distal fixation point of Talent grafts with uncovered bare springs as the distal fixation. Both of these patients were treated with an immediate endovascular placement of a limb extension. Both of these patients did well in the perioperative period. The one patient in whom the case was aborted had a small calcified aortic bifurcation. We were unable to access the aneurysm sac for device delivery. This event could have been prevented if the surgeon had chosen an aorto–uni-iliac rather than a bifurcated design system. This patient was subsequently successfully treated with such a design. In summary, in our retrospective analysis of these adverse events, we would not have rejected any of the patients who experienced an intraoperative major adverse event. Since these early cases, we have learned to avoid ballooning across the bare springs of the distal fixation point of the Talent grafts. We gained increased experience in the design phase and intraoperative troubleshooting. For example, we could have chosen an aorto–uni-iliac design rather than a bifurcated design for a small calcified bifurcation. Also, by using a single-wire technique from the brachial artery to the femoral artery, severe access problems related to tortuosity and calcification can be significantly improved, such as to avoid crimping of the delivery system at angulated sites along the vasculature and to avoid undue pressure transmission to the aneurysm sac with the leading end of the delivery system.

We conclude that gender-related differences in the incidence of complex aneurysm morphologic features and narrow native vasculature may preclude widespread applicability of aortic endografting, in women, as seen from our experience with the Ancure and Talent devices. In addition to a significantly reduced iliac artery size, women are more likely to have a shorter, more angulated, more dilated infrarenal aortic aneurysm neck. It is recommended that new design concepts and evolving technology should be combined with the clini-

cal data, with the ultimate goal of increasing the applicability of the endovascular approach across both genders.

REFERENCES

1. Katz DJ, Stanley JC, Zelenock GB. Gender differences in abdominal aortic aneurysm prevalence, treatment, and outcome. J Vasc Surgery 1997;25:561-8.
2. Semmens JB, Norman PE, Lawrence-Brown MM, Holman CD. Influence of gender on outcome from ruptured abdominal aortic aneurysm. Br J Surg 2000;87:191-4.
3. Henretta JP, Hodgson KJ, Mattos MA, Karch LA, Hurlbert SN, Sternbach Y, et al. Feasibility of endovascular repair of abdominal aortic aneurysms with local anesthesia with intravenous sedation. J Vasc Surg 1999;29:793-8.
4. Blum U, Voshage G, Lammer J, Beyersdorf F, Tollner D, Kretschmer G, et al. Endoluminal stent-grafts for infrarenal abdominal aortic aneurysms. N Engl J Med 1997;336:13-20.
5. Brewster DC, Geller SC, Kaufman JA, Cambria RP, Gertler JP, LaMuraglia GM, et al. Initial experience with endovascular aneurysm repair: comparison of early results with outcome of conventional open repair. J Vasc Surg 1998;27:992-1003.
6. May J, White GH, Yu W, Ly CN, Waugh R, Stephen MS, et al. Concurrent comparison of endoluminal versus open repair in treatment of abdominal aortic aneurysms: analysis of 303 patients by life table method. J Vasc Surg 1998;27:213-20.
7. Zarins CK, White RA, Schwarten D, Kinney E, Diethrich EB, Hodgson KJ, et al. AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. J Vasc Surg 1999;29:292-305.
8. Zarins CK, White RA, Fogarty TJ. Aneurysm rupture after endovascular repair using the AneuRx stent graft. J Vasc Surg 2000;31:960-70.
9. Food and Drug Administration. P99017: Summary of safety and effectiveness data, tube and bifurcated and ANCURE systems. In: Center for Devices and Radiological Health. Rockville (MD): National Press Office; 1999.
10. Naslund TC, Edwards WH Jr, Neuzil DF, Martin RS III, Snyder SO Jr, Mulherin JL Jr, et al. Technical complications of endovascular abdominal aortic aneurysm repair. J Vasc Surg 1997;26:502-9.
11. May J, White GH, Waugh R, Stephen MS, Chaufour X, Yu W, et al. Adverse events after endoluminal repair of abdominal aortic aneurysms: a comparison during two successive periods of time. J Vasc Surg 1999;29:32-7.
12. Buth J, Laheij RJ, on behalf of EUROSTAR Collaborators, Eindhoven, The Netherlands, and Liverpool, United Kingdom. Early complications and endoleaks after endovascular abdominal aortic aneurysm repair: report of a multicenter study. J Vasc Surg 2000;31:134-46.
13. Ahn SS, Rutherford RB, Johnston KW, May J, Veith FJ, Baker JD, et al. Reporting standards for infrarenal endovascular abdominal aortic aneurysm repair: Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/International Society for Cardiovascular Surgery. J Vasc Surg 1997;25:405-10.
14. Beebe HG, Bernhard VM, Parodi JC, White GH. Leaks after endovascular therapy for aneurysm: detection and classification. J Endovasc Surg 1996;3:445-8.
15. Alimi YS, Chakfe N, Rivoal E, Slimane KK, Valerio N, Riepe G, et al. Rupture of an abdominal aortic aneurysm after endovascular graft placement and aneurysm size reduction. J Vasc Surg 1998;28:178-83.
16. Torsello GB, Klenk E, Kasprzak B, Umscheid T. Rupture of abdominal aortic aneurysm previously treated by endovascular stentgraft. J Vasc Surg 1998;28:184-7.
17. Nasim A, Thompson MM, Sayers RD, Boyle JR, Bolia A, Bell PR. Late failure of endoluminal abdominal aortic aneurysm repair due to continued aneurysm expansion. Br J Surg 1996;83:810-1.
18. Naydeck BL, Sutton-Tyrrell K, Schiller KD, Newman AB, Kuller LH. Prevalence and risk factors for abdominal aortic aneurysms in older adults with and without isolated systolic hypertension. Am J Cardiol 1999;83:759-64.
19. Englund R, Hudson P, Hanel K, Stanton A. Expansion rates of small abdominal aortic aneurysms. Aust NZ J Surg 1998;68:21-4.
20. Starr JE, Hertzer NR, Mascha EJ, O'Hara PJ, Krajewski LP, Sullivan TM, et al. Influence of gender on cardiac risk and survival in patients with infrarenal aortic aneurysms. J Vasc Surg 1996;23:870-80.
21. Lederle FA, Johnson GR, Wilson SE, Gordon IL, Chute EP, Littooy FN, et al. Relationship of age, gender, race, and body size to infrarenal aortic diameter: The Aneurysm Detection and Management (ADAM) Veterans Affairs Cooperative Study Investigators. J Vasc Surg 1997;26:595-601.

Submitted June 12, 2000; accepted Sep 27, 2000.