

Thoracic Aortic Endografting Is the Treatment of Choice for Elderly Patients With Thoracic Aortic Disease

John A. Kern, MD,* Alan H. Matsumoto, MD,† Curtis G. Tribble, MD,* Leo M. Gazoni, MD,* Benjamin B. Peeler, MD,* Nancy L. Harthun, MD,* Tae Chong, MD,* Kenneth J. Cherry, MD,* Michael D. Dake, MD,† John S. Angle, MD,† and Irving L. Kron, MD*

Objective: To assess the effect of age on outcomes following thoracic aortic endografting.

Summary Background Data: Endograft therapy for thoracic aortic disease is rapidly evolving. This therapy is less invasive, and elderly patients with significant medical comorbidities are more frequently referred for endografting. We hypothesized that elderly patients over the age of 75 have worse outcomes after thoracic endografting than patients under the age of 75.

Methods: We retrospectively reviewed the charts of the first 42 patients who underwent endografting for thoracic aortic pathology. Charts were reviewed for demographics, comorbid conditions, perioperative complications and death, endoleaks, and results at 3, 6, and 12 months. Preexisting medical conditions were also evaluated to determine if any patient characteristics were associated with adverse outcomes. Perioperative morbidity included cardiac, pulmonary, renal, hemorrhagic, and neurologic (stroke and spinal cord injury) complications.

Results: Twenty-four patients were under the age of 75, and 18 patients were 75 or older. Baseline demographics and comorbidities were similar between the 2 groups. There were no differences in operative time, length of stay, perioperative mortality, or the incidence of significant complications between the 2 age groups. Gender, however, was associated with a statistically significant difference between the occurrence of complications, with more women experiencing complications than men ($P = 0.026$, relative risk = 2.36). One patient (age >75 years) in the entire cohort of 42 (2.4%) suffered a spinal cord injury. At 3 months, endoleaks were more common in the older age group ($P = 0.059$).

Conclusion: Endograft therapy for thoracic aortic disease can be performed safely in elderly patients with no significant increase in perioperative morbidity or mortality compared with younger patients. Female gender is associated with a higher likelihood of perioperative complications, regardless of age. The overall incidence of spinal cord injury is very low. Endograft therapy, when anatomically possible, is the treatment of choice for thoracic aortic disease in elderly patients.

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From the Departments of *Surgery and †Radiology, University of Virginia Health System, Charlottesville, VA.

Reprints: John A. Kern, MD, P.O. Box 800679, University of Virginia Health System, Charlottesville, VA 22908-0679. E-mail: jak3r@virginia.edu.

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Endovascular therapy for thoracic aortic aneurysms, penetrating ulcers, traumatic transections, and other diseases of the aorta is rapidly progressing. Presently, one device is FDA approved and commercially available in the United States for the treatment of thoracic aortic aneurysms, and at least 2 other devices are in clinical trials. Compared with conventional open surgery, endograft repair is associated with a shorter hospital stay, improved early recovery, and lower perioperative morbidity and mortality rates.¹ This is particularly well studied in the treatment of abdominal aortic aneurysms and is becoming increasingly well documented for thoracic aortic aneurysms as well.²

The influence of age on outcomes following endovascular treatment of the thoracic aorta is less well documented. Previous studies have demonstrated higher perioperative complication rates for elderly patients undergoing conventional open aortic surgery compared with younger patients, and age is often found to be an independent risk factor for postoperative complications following thoracic aortic surgery.^{3–5} Because older patients are more likely to be afflicted with comorbid medical conditions, which may have a negative impact on open surgical outcomes, endovascular therapy may be ideally suited for such patients. The influence of age, independent of other medical comorbidities, is not fully understood with regards to its impact on outcomes following thoracic aortic endografting. Based on the studies on open thoracic aortic surgery, we hypothesized that elderly patients (over the age of 75) have worse outcomes than their younger counterparts (patients under the age of 75) following endovascular treatment of the thoracic aorta.

METHODS

This study was reviewed and approved by the Human Investigation Committee of the University of Virginia Health System. Data were retrospectively analyzed after being collected and stripped of all patient identifiers. This retrospective hospital and chart review was carried out on the first 42 consecutive patients undergoing endovascular stent graft therapy for thoracic aortic aneurysms, penetrating ulcers, intramural hematomas, or traumatic aortic injuries, and included all patients undergoing thoracic aortic endografting at the University of Virginia from 1999 through October 2005. Patients were offered endografting based on the availability of an endograft (during clinical trials prior to FDA approval)

and appropriateness of anatomy. No patients were excluded or included specifically based on the presence or absence of other medical conditions. Patients deemed not to be candidates for conventional open surgery were offered endografting only if they had appropriate vascular anatomy.

Patients were divided into 2 groups: those under the age of 75 and those 75 years or older. Baseline demographics and preexisting medical conditions were documented and recorded for each patient and are demonstrated in Table 1. The groups were analyzed and compared for their preexisting medical conditions, operative times, hospital stay, complications (including hemorrhagic, renal, cardiac, pulmonary, neurologic, and peripheral ischemic), as well as for the presence of an endoleak (diagnosed with CT or MR angiography) within the first 1, 3, 6, or 12 months postoperatively. Aneurysm expansion and the subsequent need for reintervention (due to expansion or endoleak) as well as early and late mortality were also evaluated. The groups were evaluated for differences in adverse events and results, and a risk factor analysis was done to identify any significant predictors of adverse outcomes.

All patients underwent thoracic aortic endografting using either a commercially available device or a manufactured device as part of an FDA-approved clinical protocol. All devices were inserted through the femoral or iliac artery, either through a direct arteriotomy, a Dacron conduit, or a percutaneous route. All patients received general anesthesia. Patients who underwent endografting of their thoracic aorta simultaneously during another operation or through an ascending aortic conduit through a sternotomy were excluded from this study. All patients underwent preoperative CT or MR angiography to size the device and plan the procedure, while digital subtraction angiography and intravascular ultrasound were used selectively or as required by clinical protocols. Patients underwent postoperative imaging (CT or MR angiography) at 1, 3, 6, and 12 months postoperatively, or as mandated by clinical protocols.

Four patients (3 younger than 75 years, 1 older than 75 years) underwent pre-endograft carotid to subclavian artery bypass or subclavian artery transposition to allow safe coverage of the left subclavian artery and provide an adequate proximal landing zone for the endograft. These patients had evidence of an incomplete circle of Willis with dependence

on the left vertebral artery, or were left vertebral artery dominant based on preoperative CT or MR angiography. No patients suffered complications from these adjunctive procedures. One patient (younger than 75 years) underwent celiac artery embolization prior to her endograft to obtain an adequate distal landing zone. This patient had adequate collateralization of her celiac artery through her superior mesenteric artery as documented by arteriography and had no complication as a result of her celiac artery embolization or subsequent endografting.

Statistical Analysis

Measurements for quantitative variables are reported as mean \pm standard error of the mean (SEM). Student 2-sample *t* tests were used to determine if these variables were significant risk factors. A univariate analysis of the qualitative variables was performed using either a χ^2 analysis or a Fisher exact test. Relative risk was computed to determine the strength associated with certain risk factors. Results were determined to be significant using the 5% significance level. Kaplan-Meier curves, and mean and median implant days were evaluated for both groups.

RESULTS

Thoracic endografting was successfully accomplished in all patients. The age range in the under 75 group was 29 to 74 with a mean \pm SEM of 62.4 ± 2.8 (SEM) years. The age range in the 75 and over group was 75–82 with a mean of 78.6 ± 0.5 (SEM). All patients underwent endografting for focal aneurysmal disease, symptomatic penetrating ulcer or intramural hematoma, or traumatic aortic injury. All patients with traumatic aortic injury were in the younger age group. None of the patients in either group had frank leak or rupture at the time of endografting, and no patients were treated emergently. Hypertension was the only pre-existing comorbidity that was more frequent in the older age group, but this did not reach statistical significance ($P = 0.076$). All other pre-existing comorbid conditions were similar between the 2 groups as shown in Table 1. There were more females in the younger age group ($P = 0.032$). Kaplan-Meier curves for length of implant and mean and median length of implant were not statistically different between the 2 groups (Fig. 1).

Measured outcomes were similar between the 2 age groups (Table 2). Operative time, length of hospital stay, the need for blood transfusions, and significant postoperative complications (pulmonary, renal, cardiac, neurologic, hemorrhagic, and embolic) were not statistically different between the 2 groups. Mean length of stay in the older group was 9.7 ± 3.6 (SEM) days and ranged from 2–66 days, while mean length of stay in the younger group was 10.0 ± 2.2 (SEM) days and ranged from 2 to 40 days. Ten of the 18 patients 75 years or older (56%) and 12 of the 24 patients younger than 75 years (50%) were discharged in under 5 days.

The overall stroke rate was 7.1% (11% in the older group vs. 4.2% in the younger group, $P = 0.57$) and the overall spinal cord injury rate was 2.4% (5.6% in the older group vs. 0% in the younger group, $P = 0.43$). None of the strokes was fatal. One patient (under 75) who underwent pre-endografting carotid to subclavian artery bypass had a

TABLE 1. Patient Characteristics

	74 and Under (n = 24)	75 and Over (n = 18)	P
Age	62.4 \pm 2.8	78.6 \pm 0.5	0.0000031
Gender (M:F ratio)	1:2	2:1	0.03
Hypertension	58.3%	83.3%	0.08
Renal insufficiency	12.5%	11.1%	0.69
CVA	12.5%	27.8%	0.26
COPD	33%	33%	1.00
CAD	33%	33%	1.00
PVD	17%	33%	0.28

CVA indicates cerebrovascular accident; COPD, chronic obstructive pulmonary disease; CAD, coronary artery disease; PVD, peripheral vascular disease.

Kaplan-Meier Curves for Implant Days to Last Follow-Up

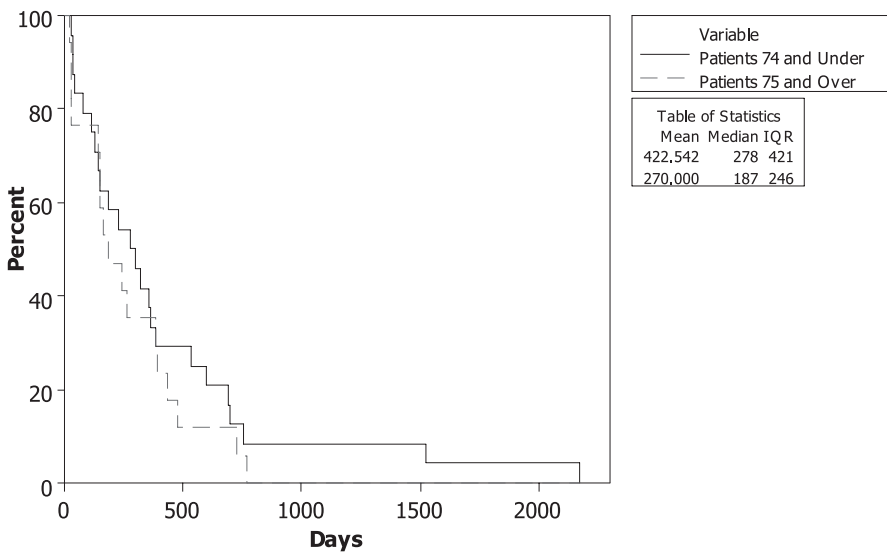


FIGURE 1. Kaplan-Meier curve evaluating implant days for both groups with mean and median follow-up.

stroke during the endograft procedure. There was one early death in the entire series, yielding a procedure related mortality rate of 2.4% (5.6% in the older group vs. 0% in the younger group, $P = 0.43$). The single death occurred in a 77-year-old woman with postprocedural pulmonary insufficiency (requiring a tracheostomy), renal failure, and spinal cord injury. There were no other spinal cord injuries in the entire series. Pulmonary insufficiency was the most common complication seen in the older group, occurring in 22% of these patients versus 8.3% in the younger group ($P = 0.38$). Two patients, both in the older age group, required a tracheostomy. While all immediate postoperative complications were evenly distributed between the 2 age groups (Fig. 2), female gender was a risk factor for complications in general ($P = 0.026$, relative risk 2.36), and was a strong risk factor for pulmonary complications ($P = 0.022$) (Fig. 3).

Endoleaks were seen with equal frequency in both groups within the first month after endografting (22% in the older group vs. 12.5% in the younger group, $P = 0.44$), but by 3 months were seen more commonly in the older patients (38.5% vs. 5.6%, $P = 0.059$) (Fig. 4). Immediate type I endoleaks

occurred in 2 patients in the younger group and in one patient in the older group. One of the younger patients with a type I endoleak had spontaneous resolution of his endoleak by 1 month while the other 2 patients were treated with catheter-based embolization when the endoleak persisted for more than 1 month. This was unsuccessful in both patients; however, one was then treated successfully with an endograft extension. A total of 6 of the 42 patients required secondary endovascular interventions for worsening or persistent endoleaks, with or without aneurysm expansion or extension. In addition to the 3 patients with type I endoleaks, 3 other patient underwent endograft extension or “repaving” to treat either a type II or type III endoleak, or aneurysm extension beyond the original endograft. No significant complications or deaths resulted from the secondary interventions. Secondary interventions were successful in 4 of the six. To date,

TABLE 2. Postoperative Outcomes

	74 and Under (n = 24)	75 and Over (n = 18)	P
Length of stay (days)	10 ± 2.2	9.7 ± 3.6	0.96
Operative time (min)	205.8 ± 20	176.8 ± 70	0.28
Blood transfusion (%)	25	16.7	0.71
Death (%)	0	5.6	0.43
Endoleaks (%)	12.5	22.2	0.44
Stroke rate (%)	4.2	11.1	0.57
Spinal cord injury (%)	0	5.6	0.43
Pulmonary complication (%)	8.3	22.2	0.38
Cardiac complication (%)	0	11.1	0.18
Renal failure (%)	8.3	5.6	1.00

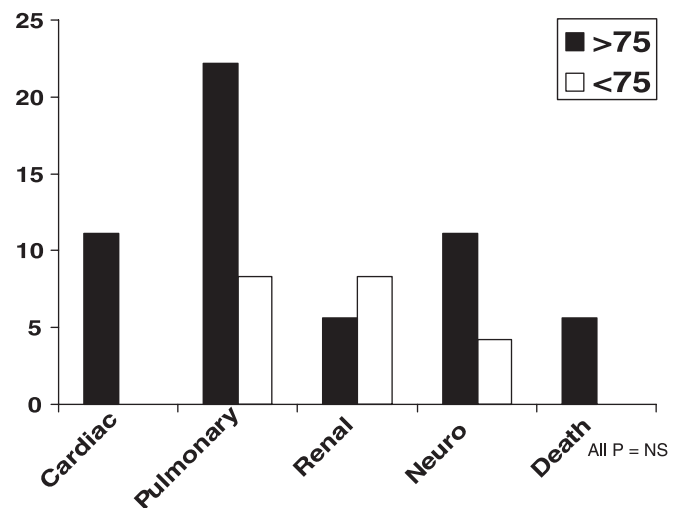


FIGURE 2. Comparison of complications after endovascular treatment with respect to age group.

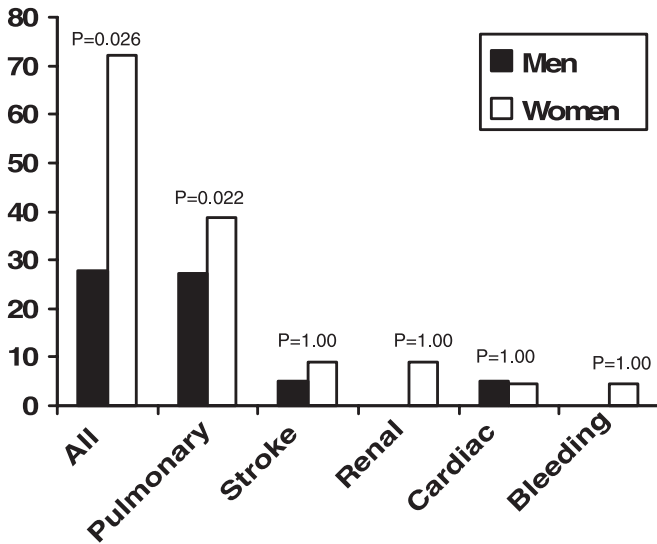


FIGURE 3. Comparison of complications after endovascular treatment with respect to gender.

isolated type II endoleaks through patent intercostal arteries alone have not required treatment because these have not been associated with aneurysm expansion.

DISCUSSION

The natural history of many thoracic aortic disease processes is becoming better understood. While the tendency at times may be to not offer elective surgery to older patients with thoracic aortic aneurysms because of the increased surgical risk associated with a thoracotomy and aortic cross clamping in this frail population, the natural history of many untreated thoracic aortic diseases can be unfavorable. Kawachi et al performed a comparative study of the natural history and operative results in patients older than 75 years with thoracic aortic aneurysms.⁶ These authors concluded that patients over 75 years with asymptomatic thoracic aneurysms over 6 cm should undergo an elective operation if they are in generally good condition. In this study, the 3-year survival rate was 41% for patients undergoing nonsurgical observational man-

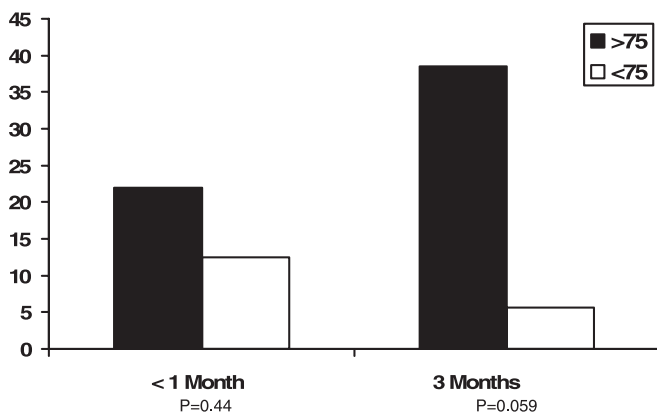


FIGURE 4. The percentage of endoleaks within the initial month after treatment and 3 months after treatment.

agement, versus 83% for patients undergoing successful elective open surgical repair. In a similar fashion, Davies et al performed a retrospective review of 570 patients with thoracic aortic diseases.⁷ Five-year survival in patients not operated on was 54% and aneurysm size was a very strong predictor of rupture, dissection, and mortality. In this study, death, rupture, or dissection occurred at a rate of 15.6% per year for patients with an aneurysm greater than 6 cm. The authors concluded that elective repair should be considered for patients with aneurysms greater than 6 cm.

While the natural history of thoracic aortic aneurysms greater than 6 cm is often less than favorable, the surgical treatment, particularly of elderly patients, can be a formidable challenge. Although associated medical comorbid conditions are often responsible for less than ideal results following open thoracic aortic surgery in elderly patients, studies have shown that increasing age is itself a predictor of operative mortality and poor outcomes. Coselli et al performed a risk factor analysis in 1220 consecutive patients undergoing thoracoabdominal aneurysm repair from 1986 to 1998 using multiple logistic regression with stepwise modeling.³ For elective cases, increased age was a strong predictor of operative mortality. In a later study by Coselli et al, multivariable analysis revealed that increased age, along with renal insufficiency, and increased red cell transfusion requirements were the 3 predictors for mortality following open surgical repair in patients with Crawford extent II thoracoabdominal aneurysms.⁸

In a large study that illustrated the difficulties of operating on elderly patients with thoracic aortic aneurysms, Okita et al reviewed the results of over 1000 patients who underwent standard open surgery for thoracic aortic disease between 1978 and 1997.⁵ In this study, 261 patients were 70 years or older and were compared with 896 patients under the age of 70 years. Early mortality, postoperative stroke, respiratory difficulties, and time in the intensive care unit were all significantly worse in the elderly group of patients. Even in the most contemporary patients (1991–1997), 30 days in hospital postoperative mortality was significantly higher in the older patients versus the younger patients (15.6% vs. 8.6%, $P = 0.03$). Logistic regression analysis revealed that age over 70 years was one of 7 patient-related preoperative variables that were significant risk factors for postoperative hospital death. In a similar type of review, Miller et al used a complex statistical analysis to describe the 30-day rate of renal failure, neurologic deficit, stroke, or death following thoracoabdominal aneurysm repair in 841 patients.⁴ Age was 1 of only 5 predictors for at least 1 of the 4 adverse outcomes.

The development of aortic endografting and the application of this technology to treat thoracic aortic disease were first described in the early 1990s. Dake et al reported in 1994 on the feasibility of stent-grafts to treat descending thoracic aortic aneurysms, including dissections.⁹ While the maturation of stent-graft technology has significantly changed the treatment algorithm for patients with abdominal aortic aneurysms over the last several years, the widespread use of this technology to treat thoracic aortic pathology has lagged behind. In general, patients with thoracic aortic aneurysms, particularly those who are older, face higher risks with

standard open surgery, and may derive more benefit from stent-graft therapy than their counterparts with aneurysms limited to the infrarenal aorta. However, despite the logical assumption that high-risk and elderly patients with thoracic aortic aneurysms would fare better with less invasive therapy, little data are available to support this notion. The EUROSTAR collaborators recently reported their results with endografting in patients over the age of 80 years with abdominal aortic aneurysms and compared them with patients younger than 80 years.¹⁰ Whereas the authors concluded that endovascular aneurysm repair should be considered for elderly patients with appropriate anatomy, the 30-day in-hospital mortality was higher in the octogenarians compared with the younger patients (5% vs. 2%, $P < 0.0001$). In addition, more device-related complications, systemic complications, and bleeding complications were noted in octogenarians. Another recent report by the EVAR participants evaluated the results of endografting for abdominal aortic aneurysms.¹¹ For many high-risk elderly patients with abdominal aortic aneurysms over 5.5 cm, close observation may yield similar survival rates as endovascular treatment.

Ehrlich et al in 1998 compared the results of endografting versus open surgery for the treatment of descending thoracic aortic aneurysms.¹² In this report, 68 patients underwent replacement of the thoracic aorta: 58 underwent conventional open repair and 10 underwent endografting with a commercially manufactured device. The 30-day mortality in the conventional surgery group was 31% versus 10% in the patients undergoing endografting. In addition, operative time, spinal cord injury rate, ICU, and hospital stay were all significantly higher in the conventional surgery group. This was one of the first studies to document the benefits of endografting over conventional surgery for the treatment of thoracic aortic aneurysms. Other studies have corroborated the benefits of endografting for thoracic aortic disease, but few have evaluated the impact of patient age. Two independent case-controlled studies evaluating the short-term and midterm results of endografting for descending thoracic aortic disease have demonstrated improvements in perioperative morbidity, ICU and hospital stay, and hospital costs, with one study showing lower 30-day mortality and comparable complication rates in older patients compared with those undergoing open surgery.^{13,14} Improvements in midterm and long-term life expectancy, however, have yet to be realized in older patients undergoing endografting for thoracic aortic disease. One other recent study, in addition to our present study, evaluated age as a determinant of postinterventional outcome following thoracic aortic endografting. Eggebrecht et al evaluated the determinants of outcome following stent-graft treatment of aortic dissection.¹⁵ Multivariable analysis revealed that poor preoperative clinical health status (ASA >3) and increased age were the only independent determinants of postinterventional mortality.

Our present study was undertaken to test the hypothesis that older patients fare more poorly than younger patients following thoracic aortic endografting. All thoracic aortic disease processes other than chronic dissections were included in this review. In our study, medical comorbidities and demographic characteristics were remarkably similar between the

TABLE 3. Gender Comparison

	Male	Female	<i>P</i>
Age	73.3 ± 2.0	65.8 ± 3.2	0.06
Operative time (min)	149.6 ± 13	234.6 ± 20	0.001
% of all complications	27.8	72.2	0.026
Length of stay (days)	6.4 ± 1.6	13 ± 3.3	0.08

older and younger age groups. Operative time, the need for blood transfusions, postoperative complications, and length of hospital stay were similar between the 2 groups. Only one early postoperative death occurred in the entire series (1 of 42, 2.4%). Although this death occurred in the older age group, there was no statistically significant difference in mortality between the younger and older patients. In addition, the rate of spinal cord injury was also very low (2.4% overall) and no different between the 2 age groups. The mortality and spinal cord injury rates observed in our present study compare favorably to all contemporary reports of open surgical repair of thoracic aortic aneurysms.¹⁶ A persistent endoleak at 3 months was the only complication that was more commonly seen in the older patients. Whether or not this complication will predictably lead to recurrent interventions and predispose these patients to further risk is unknown. Six patients have undergone secondary interventions to treat persistent or worsening endoleaks, with success in four of the six. Fortunately, no procedure-related complications have resulted from these secondary interventions. While other studies have demonstrated a cost benefit with thoracic aortic endografting as compared with open thoracic aortic surgery, it is unclear if this benefit will be durable given the need for continued follow-up, imaging, and the potential for secondary interventions required for endograft patients.¹⁴ One unexpected finding in our study was the significance of female gender and its association with more complications (relative risk 2.36, $P = 0.026$). This was in spite of the fact that females were more prominent in the younger age group. Female gender was also associated with longer operating times; and while it is possible the longer operating times were due to smaller vessels and the greater need for access conduits, whether or not this should have resulted in more complications is unclear (Table 3).

CONCLUSION

Our data demonstrate that older patients do as well as their younger counterparts after thoracic aortic endografting. While this study has several limitations, including those of being a retrospective review, being nonrandomized, and having no direct comparison to conventional surgical patients, we believe the data lend support to the use of endograft repair of thoracic aortic diseases in the elderly. Age alone should not be a criterion for withholding endograft therapy from patients with thoracic aortic aneurysms, intramural hematomas, or penetrating ulcers. Although advanced age is an independent risk factor for mortality after open thoracic surgery, in our experience, it does not appear to be a risk factor for mortality after thoracic aortic endografting. These data support the assumption that older patients with thoracic

aortic pathology should be considered for thoracic aortic stent-grafts if the anatomy is suitable.

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Discussions

DR. JOHN W. HAMMON, JR. (WINSTON-SALEM, NORTH CAROLINA): I would like to make a comment related to the title of the manuscript. When I first read this I got very excited, hoping that we were going to see a comparison between endografting of the thoracic aorta with the very excellent

series that the University of Virginia has in open repair of thoracic aortic aneurysms. I suspect that is going to have to wait for a future publication. At any rate, I do feel that there are a couple of areas here that have been brought out in the presentation that I would like to elaborate on and maybe ask a couple of questions.

The first, and as you said, a very unexpected finding, was that of gender; 72% of all the complications in this series occurred in women. Plus, many of the women were in the younger age group. It is obvious that this fits into the same classification as stenting of coronary disease, coronary bypass surgery, in that women have a higher incidence of complications, and perhaps mortality. I am wondering if you have any thoughts on this. Does this have to do with the learning curve? Were there more women early in the series? Does it have to do with perhaps bulkier devices? I think it is very important that we try and understand this phenomenon.

There were very few differences between the older and the younger group overall, particularly related to complications, although late endoleaks were more common in the older group. Since this series has only been followed for a year, I was wondering if you had any speculation as to if you think these late endoleaks, which may be related perhaps to calcification of the landing zone or tortuosity of vessels, are going to make the late results worse in the elderly patients.

I would also like to have you give us some information, if you could for educational value, on the number of patients during this time period that were seen, evaluated, and operated using an open technique for thoracic aortic aneurysm so that we understand the differences in selection between these two groups.

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): From the standpoint of being able to do a direct comparison of open repair versus endografting in older patients, although we do a large volume of thoracic aortic surgery and this endograft experience represents probably about one third to one half of our practice, it is too difficult, I believe, to get enough numbers to accurately answer that question. The influence of age on open thoracic aortic surgery is well documented in the literature, and we simply wanted to review our experience with endografting to see if age is an important risk factor when it comes to endografting these older folks, as it is in conventional surgery. The issue of the significance of female gender is a finding that was totally unexpected. I don't know that we have a good explanation for this. Certainly, we need to give it more thought. It might be something along the lines, as you pointed out, as with our experience in coronary stents in females. One of our hypotheses, however, from the standpoint of aortic endografting, is that women in general have smaller vessels, which prompted the need for more cut-down procedures on the iliacs and even the distal aorta.

Even though most of these patients were operative candidates, meaning they were safe for general anesthesia,

not all of them were. Having said that, all of them did get general anesthesia. So it might be just a compilation of several small factors leading up to the fact that in the long run, statistically, women did more poorly with more complications. However, it did turn out to be a significant difference for the female gender.

The late endoleak issue continues to be a problem. We really generated the greatest number of these patients over the last year. So we don't have very long follow-up for the majority of these patients. In addition, within our experience, we have essentially used three different devices during the study period. We did not do a subgroup analysis to see if the device played a role in the presence of late endoleaks. We simply did not have enough numbers, I believe, to do a subgroup analysis. Patients treated in the early part of our experience were treated with the Medtronic AneuRx device, which, we believe, has a little stiffer radial hoop strength. The device most commonly used now is the FDA-approved Gore TAG device, which, we believe, has a little less radial hoop strength. This may be important because our first 4 or 5 patients who underwent treatment with the AneuRx device essentially developed no late endoleaks. So we may be finding, that if you have a patient who is a bit older and who has more calcium in the landing zone, a device with more radial hoop strength may be beneficial.

DR. JULIE ANN FREISCHLAG (BALTIMORE, MARYLAND): I had a few questions. A couple of them were taken by Dr. Hammon.

But in your open group which you had, have you seen this gender factor as well? Do your women in the group that you take care of open, do they have more complications? Because in the abdominal aortic aneurysm endovascular group, women had more trouble, but it was mainly in device deployment. Once the device was in by the conduit, or was aborted, they started to still do as well. It was not complications following the procedure which you really saw in your results here.

What is your follow-up time? I was a little unclear about your average follow-up time for your group of patients. It sounds like it is somewhere between 3 months and 12 months, but I don't think you told us.

In the prospective randomized study we are doing in the V.A. of endograft versus open for infrarenal aneurysms, we have randomized almost 560 patients now. They gave us 5 million more dollars, so we are hoping to get to almost a thousand. And we find, after the first year, they tend to still have as many troubles in the endogroup as the open group. The halo effect of having a more minimal operation goes away and they start getting their cancer, heart disease, and more endoleaks. So certainly watching later, that is certainly what we are finding now that we are 3 and a half years into ours.

Have you done emergent patients? We find that is probably the most important group to have this available for, because those do so poorly. If so, how was your outcome?

And the pulmonary complications. I thought you would avoid the pulmonary complications of these patients because that really does them in, at least a fourth of them. And I am just amazed you had such a high increase of pulmonary complications, even though you didn't make that big incision on the chest.

And my final question was about your technique of treating the endoleaks, which may be beyond this group but I am interested. Embolization of a proximal endoleak has not worked in infrarenal aortic aneurysms, and one of yours did and one didn't. What did you use and what did you do to the one that failed? You also had one extension that didn't work. What did you do with that patient? Are you just watching those 2 patients to see if the aneurysm grows?

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): This is a very good question, and I really cannot answer for sure whether or not we see more complications in our female patients who have undergone open thoracic aortic surgery. It in general has not been my impression; however, we have not looked at it scientifically.

In terms of the follow-up, this is a tricky issue. If you look at the median follow-up time for this group, it is somewhere in the 30-month range. Perhaps not quite that long. The mean follow-up is quite short, probably somewhere around 12 months.

How things are going to pan out down the road, we cannot say for sure. I am a bit concerned about the potential lack of radial hoop strength for the FDA-approved Gore device and how this may prove to be more of an issue, particularly as we try to treat lesions other than aneurysmal disease and lesions close to the aortic arch.

Up to this point in time, we have not done any emergent procedures; well, we have done one very recently. We have, however, done several urgent patients, and I have no reason to suspect that doing these patients on an emergent basis will necessarily pan out any differently. It is simply a matter of having enough stock on the shelves, which gets into a cost issue.

In terms of the surprising rate of pulmonary complications, which is the one thing that we thought we would see a lot less of, I think our numbers are still a bit too small to make any sound conclusions. Again, even though the bulk of these patients were indeed operative candidates, there were about 8 of them which were clearly less than ideal open thoracic aortic surgery candidates. As we know, one of the reasons patients are not candidates for open thoracic aortic surgery is usually for pulmonary issues. Having said that, all of the patients did indeed undergo general anesthesia. As a result, I think there as a small group of patients who were quite frail from a pulmonary standpoint who nevertheless underwent

general anesthesia; in addition, they may have been female patients requiring an aortic or iliac cut-down, and as a result, the complications were more likely seen in this group.

In terms of the techniques utilized for treating the endoleaks, that is an evolving process. Depending on the location of the original aneurysm and the length of the landing zones, sometimes if an endoleak is a proximal or distal type I endoleak, additional stent grafts can be placed. Treatment of type II endoleaks, however, could prove to be a bit trickier. Fortunately, we have had no patients with aneurysm growth in whom we have seen a type II endoleak.

We have had 2 patients die with type I endoleaks who we have intervened upon endovascularly. Both of these patients were nonsurgical candidates; and in one, we were able to successfully treat the endoleak with coil embolization of the proximal type I endoleak. The other patient was unable to be treated and we simply are at a loss to be able to offer her any further treatment.

DR. ALI F. ABURAHMA (CHARLESTON, WEST VIRGINIA): I still feel like the issue of endoleak is a very critical issue to be brought before this audience. If you don't have the exact measurement of the landing zone proximally and distally, or the angulation, it is difficult to say that older patients have more endoleaks than younger patients because all of us know that you aren't dealing with the same thoracic aorta in 78-year-old patients as you are in younger patients.

Secondly, your mean operative time was surprisingly long. I noticed most of your patients had a few hours of surgery. Most of the studies so far, including our work, reported a much shorter operative time. Were there any factors in your group which made the procedure longer?

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): In terms of the endoleaks and the causes, this is true. We are learning as we are going. Every patient we do, we feel we gain a great deal of knowledge about the limits of endografting when it comes to tortuosity of the aorta. We believe the tightness of the radius of the arch is also very important. Not so much along the greater curve, but the lesser curve. All of these issues are coming into play. We are hopeful that one day we will have formulas perhaps, and even computer software, to help us figure out if we can truly treat someone endovascularly.

From the standpoint of operating time, we do our endografts in the interventional radiology suite. It is not a true standard operating room and, therefore, all of our equipment is not right outside the door. There is a fair amount of downtime that has been factored into the total operating time for these patients. We do recognize our times are a bit longer than what most other folks are reporting. It is also possible that the longer operating times may have played a role in the increased rate of pulmonary complications that we have noticed in our patients.

DR. NORMAN E. MCSWAIN, JR. (NEW ORLEANS, LOUISIANA): Realizing that this is a paper comparing ages, you did mention in answer to a previous question that you did one trauma patient. Would you elaborate a little bit on that trauma patient? What were your indications for doing it? Why did you do it? Why did you choose this over the open technique, over nonoperative management, et al? Just a couple of your thoughts as to what place this device is going to play in the management of trauma.

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): I think that is an absolutely great question, and I think we are going to really see a change in the way we treat traumatic aortic injuries. In order to avoid confusion, however, I would like to make a point. The patient that I mentioned in response to Dr. Fleischlag's question was the one patient treated as a true emergency, and this was done within the past week and was not included in our study. This study included our first 42 patients up through October of this year, who were all elective or, at the most, urgent patients. In the present study, however, there were 4 patients with traumatic aortic injuries who we treated on an urgent basis. In these 4 patients, endovascular therapy worked extremely well.

One of our patients with a traumatic aortic injury whom we treated endovascularly did indeed have a very small type I endoleak immediately after the repair. However, when we re-imaged him 1 month later, the endoleak had resolved. I think that case reflects the fact that most people with traumatic aortic injuries have otherwise normal aortas with no associated calcification or atherosclerotic disease. As a result, with a compliant aorta, I believe we will see type I endoleaks less frequently.

Whether or not we will be able to treat all patients with traumatic aortic injuries endovascularly waits to be seen. I do believe, given the fact that these patients tend to have normal aortas, that we may be able to treat patients successfully with minimal landing zones above and below the injury.

DR. L. D. BRITT (NORFOLK, VIRGINIA): I have to raise some concerns about trauma because, in all fairness, a dissection is not a rupture. A traumatic injury is a transmural rupture through all the layers of the wall with, perhaps only the adventitia intact.

So, I would ask the following question: If you feel that endovascular stenting is appropriate for trauma, should we be concerned about stent migration, the possibility of endoleak, and compliance issues? As you know, once you insert an endoluminal stent, the patient has to be followed for life! I am lucky to see my trauma patients once, much less having to follow them for life?

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): Dr. Britt, I appreciate your comments and your questions are very appropriate. As I said, however, I do believe we are learning

as we are going. Clearly, there is a spectrum of traumatic aortic injuries, from small intimal flaps to complete transections. I think patients with intimal flaps and those without complete transections, we will certainly be able to treat with very short devices and we will likely see most of those folks do well over the long term. Patients with more complete transections certainly would need to be followed much more closely to see if we are really curing them of their injury.

I have some of your same concerns over the long term for the potential of stent graft migration and what we will need to do should this occur. Obviously, we will not be able to figure this out if we cannot follow the patients longitudinally. As a result, I do believe we need to be very thoughtful and careful as we move forward in treating patients with traumatic aortic injuries and most of these patients should probably be treated at tertiary high-volume centers in whom we can make a very serious effort to make sure we follow these patients long term.

DR. MARC E. MITCHELL (JACKSON, MISSISSIPPI): My question has to deal with the left subclavian artery. In our somewhat smaller series, we find that quite frequently we have to cover the left subclavian artery. I am wondering if in your study any of the patients had the left subclavian covered and if the incidence of type 1 leaks is related to covering the left subclavian?

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): I can't say that we have looked at it statistically to say if covering the left subclavian or crossing the left subclavian and taking care of it has increased the rate of type I endoleaks. It does not appear to have done so.

From a standpoint of how we handle the left subclavian, preoperatively all patients undergo a CT angiogram or an MR angiogram of their cerebral circulation to evaluate the completeness of their circle of Willis. If their intracranial circulation is not dependent on the left vertebral artery, then we will go ahead and cover the left subclavian and not worry about performing any prophylactic carotid-to-subclavian bypass. So far, we have had no problems with this.

More interesting are those patients with aberrant left vertebral arteries coming directly off the aortic arch. In these patients, the vertebral artery is no longer a source of collateral blood flow to the arm and, as a result, we are not sure how these folks will do once you cover their vertebral and subclavian arteries. We recently have had one such patient and so far he has done well, but we are keeping a very close eye on him.

DR. EUGENE M. LANGAN, III (GREENVILLE, SOUTH CAROLINA): Two questions. When you talk about a type 1 endoleak, are you talking about proximal graft migration or are you talking about distal enlargement causing a type 2 endoleak with retrograde circulation refilling it? Number two, if you are having a problem with type 1 endoleaks, have you used IVIS in order to judge where you are going to place this to make sure that you can get a good landing zone so you don't get type 1 endoleaks?

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): When we say Type I endoleak, we mean either proximally or distally at the landing zone of the stent graft, which in essence would be the anastomosis. As a result, it is either proximal or distal. At times, it can be difficult to determine for sure whether or not someone has a type I leak or a type II or type III leak. As a result, if someone has an enlarging endoleak and certainly if their aneurysm is enlarging, these patients go back to the angio suite and undergo arteriogram to better define where the endoleak is originating. If it is a type III or IV endoleak or, if it is a type I endoleak and we have room to land more stent grafts, then we will go ahead and do so and simply repave the entire area with new grafts. Thus far, we have not used intravascular ultrasound to see if we can better identify the source of the leak because we have been able to do so through our cross-sectional and catheter-based imaging.

DR. RICHARD A. LYNN (WEST PALM BEACH, FLORIDA): I was going to ask the same question about the subclavians and the carotid and whether there were any extra-anatomic grafts having to be done.

DR. JOHN A. KERN (CHARLOTTESVILLE, VIRGINIA): We have done a few. The ones that we felt were very necessary were those patients with no right vertebral artery; therefore, the intracranial circulation was totally dependent on the left vertebral artery. Obviously, those are the easy scenarios. The patients in whom it gets a bit more difficult to figure out what to do are those with the vertebral artery coming directly off the arch in whom the intracranial circulation is maintained by the right vertebral, but we no longer have the left vertebral as a source of collateral blood flow to the arm. We have no way to figure out ahead of time if, in these patients, by covering the vertebral and subclavian artery, will the arm be okay through other sources of collateral flow. From our very small experience in 1 patient, it appears as though it is possible to do this.