Volume 66, Number 3, September 2017

SVS | Society for Vascular Surgery

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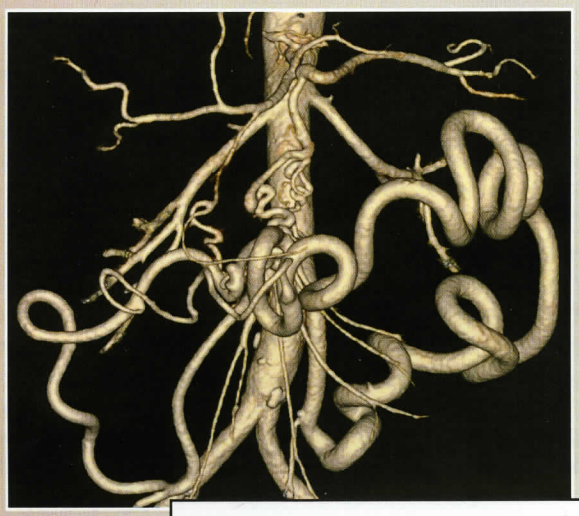
JVS Journal of Vascular Surgery

Official Publication of the Society for Vascular Surgery



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CLINICAL RESEARCH STUDIES

From the New England Society for Vascular Surgery

Outcomes of fenestrated and branched endovascular repair of complex abdominal and thoracoabdominal aortic aneurysms

Andres Schanzer, MD, Jessica P. Simons, MD, MPH, Julie Flahive, MS, Jonathan Durgin, BA, Francesco A. Aiello, MD, Danielle Doucet, MD, Robert Steppacher, MD, *and* Louis M. Messina, MD, *Worcester, Mass*

ABSTRACT

Background: More than 80% of infrarenal aortic aneurysms are treated by endovascular repair. However, adoption of fenestrated and branched endovascular repair for complex aortic aneurysms has been limited, despite high morbidity and mortality associated with open repair. There are few published reports of consecutive outcomes, inclusive of all fenestrated and branched endovascular repairs, starting from the inception of a complex aortic aneurysm program. Therefore, we examined a single center's consecutive experience of fenestrated and branched endovascular repair of complex aortic aneurysms.

Methods: This is a single-center, prospective, observational cohort study evaluating 30-day and 1-year outcomes in all consecutive patients who underwent fenestrated and branched endovascular repair of complex aortic aneurysms (definition: requiring one or more fenestrations or branches). Data were collected prospectively through an Institutional Review Board-approved registry and a physician-sponsored investigational device exemption clinical trial (G130210).

Results: We performed 100 consecutive complex endovascular aortic aneurysm repairs (November 2010 to March 2016) using 58 (58%) commercially manufactured custom-made devices and 42 (42%) physician-modified devices to treat 4 (4%) common iliac, 42 (42%) juxtarenal, 18 (18%) pararenal, and 36 (36%) thoracoabdominal aneurysms (type I, n = 1; type II, n = 4; type III, n = 12; type IV, n = 18; arch, n = 1). The repairs included 309 fenestrations, branches, and scallops (average of 3.1 branch arteries/case). All patients had 30-day follow-up for 30-day event rates; three (3%) deaths; six (6%) target artery occlusions; five (5%) progressions to dialysis; eight (8%) access complications; one (1%) paraparesis; one (1%) bowel ischemia; and no instances of myocardial infarction, paralysis, or stroke. Of 10 type I or type III endoleaks, 8 resolved (7 with secondary intervention, 1 without intervention). Mean follow-up time was 563 days (interquartile range, 156-862), with three (3%) patients lost to follow-up. On 1-year Kaplan-Meier analysis, survival was 87%, freedom from type I or type III endoleak was 97%, target vessel patency was 92%, and freedom from aortic rupture was 100%. Average lengths of intensive care unit stay and inpatient stay were 1.4 days (standard deviation, 3.3) and 3.6 days (standard deviation, 3.6), respectively.

Conclusions: These results show that complex aortic aneurysms can now be treated with minimally invasive fenestrated and branched endovascular repair. Endovascular technologies will likely continue to play an increasingly important role in the management of patients with complex aortic aneurysm disease. (J Vasc Surg 2017;66:687-95.)

The successful use of fenestrated endograft technologies for complex aortic aneurysms was first published in 1999[1,2] with subsequent iterative, more versatile fenestrated approaches published shortly thereafter by pioneers in the field.[3] Given the formidable morbidity and mortality associated with open thoracoabdominal aortic aneurysm repair,[4-9] considerable enthusiasm for minimally invasive repairs has been expressed during the nearly two decades since fenestrated endograft technologies were first described. However, relatively few centers have embraced these technologies and published their outcomes in large consecutive series of patients.[10-16]

We are currently in the midst of a rapid evolution of technical advances in endovascular catheter-based treatments for aortic aneurysms. Scallops, fenestrations, and branches can be constructed in endovascular grafts to allow stent grafts to be placed across the visceral arteries while preserving flow to the critical end organs supplied by these arteries. In this way, proximal stent graft seal zones can now be extended, well proximal to

From the University of Massachusetts Medical School.

Clinical Trial registration: NCT02025011.

Author conflict of interest: A.S. has received consulting fees from Cook Medical.

Presented at the Forty-third Annual Meeting of the New England Society for Vascular Surgery, Stowe, VT, September 23-25, 2016.

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0741-5214

http://dx.doi.org/10.1016/j.jvs.2016.12.111

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the infrarenal aorta, into areas of healthy normal aorta. Appropriate use of these technical advances requires not only the acquisition of new techniques and surgical skills but also an understanding of new, rapidly changing endovascular graft design technologies.

Our institution made a collective decision to design a strategic plan to develop a high-impact program for the endovascular treatment of complex aortic aneurysms. The initial planning stages for our complex endovascular aortic program began in 2008 and have continued to the present day.[17] The purpose of this study was to evaluate the outcomes achieved after our first 100 consecutive complex endovascular aortic procedures, each of which incorporates at least 1 branch or fenestration.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective study
- **Take Home Message:** In this single-center series of 100 consecutive endovascular repairs of complex aortic aneurysms, the perioperative mortality rate was 3%, and the 30-day adverse event rate was lower than anticipated.
- **Recommendation:** This paper suggests that complex endovascular aneurysm repair can be performed safely, with superior outcomes in centers of excellence with a dedicated aortic program.

METHODS

This is a single-center prospective observational cohort study. All data were collected prospectively through an Institutional Review Board-approved registry or physician-sponsored investigational device exemption clinical trial (G130210). All procedures were performed at one large academic hospital in a hybrid operating room with high-quality fixed radiology equipment with fusion overlay capabilities between November 2010 and March 2016. Any patient was included in the complex endovascular aortic program if the intended endovascular repair necessitated one or more fenestrations or branches to achieve a durable endograft seal. All patients included in the study were deemed at high risk for open repair by the operating surgeon and by an additional, impartial vascular surgeon reviewer. All patient data were entered into a secure, prospectively maintained database by trained research assistants. Institutional Review Board approval was obtained from the University of Massachusetts Medical School, and written informed consent was obtained for each patient.

Procedure and outcomes. All repairs were planned on the basis of measurements obtained from high-resolution computed tomography (CT) angiography images on a three-dimensional workstation using standard centerline flow orthogonal techniques (TeraRecon, Foster City, Calif).[18] For any patient's anatomy for which a commercially approved fenestrated endograft (ie, Zenith Fenestrated [ZFEN]; Cook Medical, Bloomington, Ind) or a trial device (ie, Cook Iliac Branch Device, Cook p-Branch) was available to the study team, the appropriate commercially manufactured device option was selected. Otherwise, before approval was received for our physician-sponsored investigational device exemption clinical trial in October 2013, a physician-modified device was used.[19-24] Since approval of the physician-sponsored investigational device exemption clinical trial, custom-made commercially manufactured fenestrated or branched devices have been used, unless the treating surgeon has deemed the patient's aneurysm to be at too high risk to wait the required time for manufacture, in which case a physician-modified device was used.

All patients included in the complex endovascular aortic program are observed according to a standardized protocol that consists of postoperative CT angiography at 1 month, at 6 months, and yearly thereafter. In addition, all visceral arteries that are targeted by a fenestration or a branch are evaluated with duplex ultrasound examination at 1 month, at 6 months, and yearly thereafter. All patients, in the absence of a contraindication, are prescribed clopidogrel (Plavix) for 3 months and lifelong aspirin. The 30-day follow-up was 100%, and the mean follow-up time for the entire study group was 563 days (interquartile range, 156-862), with three (3%) patients lost to follow-up.

Technical success was defined as successful delivery and deployment of the endograft with preservation of target vessel patency and absence of a type I or type III endoleak. The outcomes evaluated at 30 days included myocardial infarction (defined according to the American Heart Association's universal definition of myocardial infarction[25]), paraparesis, paralysis, stroke, deterioration in renal function (decrease in glomerular filtration rate >30%), new-onset dialysis, target artery patency, access vessel complications, presence of a type I or type III endoleak, and mortality. The outcomes evaluated at 1 year included target vessel patency, aneurysm sac enlargement (>5 mm), presence of a type I or type III endoleak, and survival. All 30-day outcomes were calculated using standard counts and proportions and are presented as number (%) or number where applicable. All 1-year outcomes were calculated using life-table analyses and the Kaplan-Meier time-to-event method. All analyses were performed using SAS 9.3 software (SAS Institute, Cary, NC).

RESULTS

Cohort description. Between November 2010 and March 2016, we enrolled 100 patients into our complex endovascular aortic disease program (1 in 2010, 7 in 2011, 14 in 2012, 22 in 2013, 13 in 2014, 31 in 2015, and 12 in the first 3 months of 2016). The average age of the

Table I. Baseline characteristics of all consecutive patients who underwent complex endovascular aneurysm repair (N = 100)

Variable	
Women	32 (32)
Age, years, mean (SD)	75 (8.7)
Comorbidities	
Coronary artery disease	55 (55)
Prior stroke	11 (11)
Chronic obstructive pulmonary disease	29 (29)
Chronic renal dysfunction	26 (26)
Diabetes	14 (14)
Cancer	26 (26)
Hypertension	85 (85)
Tobacco (current)	27 (27)
Prior abdominal endovascular aneurysm repair	11 (11)
Prior thoracic endovascular aneurysm repair	5 (5.0)
First-degree relative with aortic aneurysm	18 (18)
Aneurysm extent	
Common iliac artery aneurysm	4 (4.0)
Juxtarenal aortic aneurysm	42 (42)
Pararenal aortic aneurysm	18 (18)
Thoracoabdominal aortic aneurysm	36 (36)
Presentation	
Elective intact aneurysm	89 (89)
Urgent symptomatic aneurysm	9 (9.0)
Ruptured aneurysm	2 (2.0)

SD, Standard deviation.
Values are reported as number (%) unless otherwise indicated.

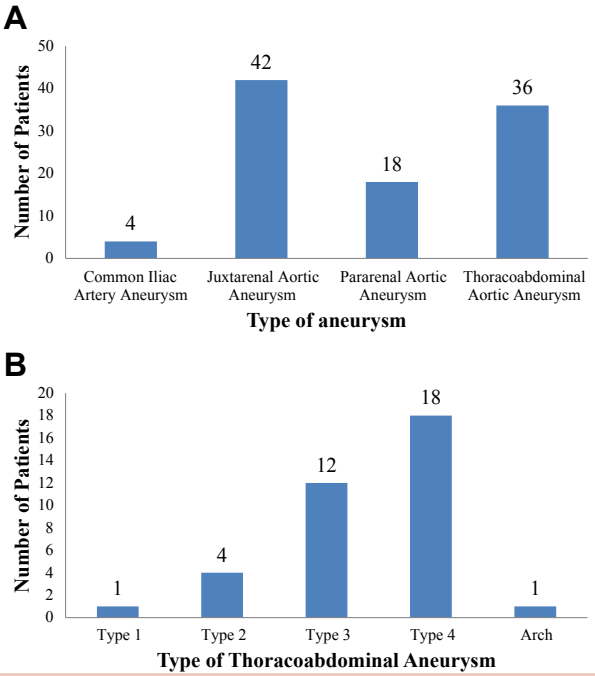

Fig 1. The number of patients who underwent complex endovascular aneurysm repair stratified according to aneurysm extent **(A)** and the thoracoabdominal aneurysm extent stratified according to the Crawford classification system **(B)**.

patients was 75 years, and 32 (32%) patients were women. Of known risk factors for aneurysm formation, 85 (85%) patients had a history of medically treated hypertension, 27 (27%) patients reported current tobacco use, and 18 (18%) patients reported a first-degree relative known to have an aortic aneurysm (Table I). For the purpose of context, during the study period, we treated a total of 795 patients for aortic aneurysm disease, of whom 333 (42%) were treated with open repair and 461 (58%) were treated with endovascular repair.

Aneurysm morphology and procedural characteristics. Of the 100 complex endovascular aortic repairs, 58 (58%) were performed using commercially manufactured devices and 42 (42%) were performed using physician-modified devices. The aneurysm extent treated included 4 (4%) common iliac, 42 (42%) juxtarenal, 18 (18%) pararenal, and 36 (36%) thoracoabdominal aneurysms (type I, n = 1; type II, n = 4; type III, n = 12; type IV, n = 18; arch, n = 1; Fig 1). The average preoperative maximum aortic aneurysm diameter or common iliac artery aneurysm diameter (if the indication for repair was a common iliac artery diameter ≥4 cm), measured using centerline technique on curved planar reformat views, was 6.2 cm (range, 4.0-11.1 cm).

The repairs included 309 fenestrations, branches, and scallops (average of 3.1 branch arteries/patient; Fig 2). Over time, the endograft design selected for complex endovascular repairs increased in complexity, with an average of 1.0, 2.3, 2.9, 3.1, 2.8, 3.4, and 3.6 incorporated target arteries per repair in 2010, 2011, 2012, 2013, 2014, 2015, and 2016, respectively (Table II). We used 0, 0, 1, 14, 4, 8, and 2 scallops in 2010, 2011, 2012, 2013, 2014, 2015, and 2016, respectively. Data pertaining to the distribution of the American Society of Anesthesiologists classification, surgery time, radiation use, and contrast material volume can be found in Table II.

Outcomes. Technical success was achieved in 89 (89%) patients. In the remaining 11 patients, 3 were found on completion study to have a type III endoleak present at the junction between a fenestration and the bridging stent graft, despite repeated attempts to flare the bridging stent graft and no evidence of component separation. For these type III endoleaks, two resolved by 1 month without intervention and one resolved after intervention with CT-guided direct sac puncture. One additional type III endoleak occurred at a renal artery fenestration that could not be bridged with a stent graft. This resolved after successful bridging stent graft placement postoperatively. Seven targeted renal arteries could not be cannulated and successfully bridged to the

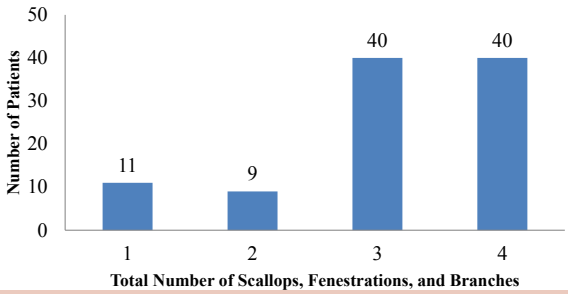

Fig 2. The total number of scallops, fenestrations, and branches used per procedure (N = 100).

fenestration with a stent graft (failure to cannulate and bridge a targeted renal artery, 7 of 185 [3.8%]; failure to cannulate and bridge any targeted artery, 7 of 309 [2.3%]).

On evaluation of 30-day outcomes, 5 (5%) patients experienced progression of chronic renal insufficiency to require dialysis (3 temporary, 2 permanent); 16 (16%) patients had a deterioration in renal function with a >30% decrease in their glomerular filtration rate; 6 (6%) patients had a target renal artery that could not be cannulated and progressed to thrombosis; 8 (8%) patients experienced access vessel complications (2 brachial artery thromboses, 2 iliac artery ruptures, 1 lower extremity bypass thrombosis, 1 femoral artery thrombosis, 2 femoral artery pseudoaneurysms); 10 (10%) patients experienced a type I or type III endoleak, of which 7 resolved after a secondary intervention and 1 resolved without intervention; 1 (1%) patient developed paraparesis (able to bear weight and to transfer but unable to walk independently); and 3 (3%) patients died (1 patient died of cardiac arrest of unknown etiology 2 days after being discharged to home on postoperative day 3; 1 patient required prolonged mechanical ventilation and was, in accordance with her family's wishes, allowed to die comfortably on postoperative day 9 after repair of a ruptured type IV thoracoabdominal aneurysm; and 1 patient was discharged home on dialysis and chose to discontinue dialysis). There were no instances of myocardial infarction, paralysis, or stroke (Fig 3). The average lengths of intensive care unit stay and inpatient stay were 1.4 days (standard deviation, 3.3) and 3.6 days (standard deviation, 3.6), respectively.

On evaluation of 1-year outcomes by life-table analysis, survival was 87%, type I or type III endoleak rate was 3.0%, and target vessel patency was 92% (six renal artery occlusions, one celiac artery occlusion; Fig 4). On follow-up imaging, one (2.0%) patient with a known type I endoleak, first detected on the 6-month surveillance CT scan, experienced aneurysm sac enlargement on 1-year imaging; he refused further intervention. To date, there have been no aneurysm ruptures, no aneurysm-related mortality events, and no physician-modified or company-manufactured endograft integrity issues (eg, stent fracture, fabric tear, migration) identified.

Table II. Procedure characteristics of all consecutive patients who underwent complex endovascular aneurysm repair (N = 100)

Variable	
Mean No. of target branch arteries included per repair stratified by year	
2010	1.0
2011	2.3
2012	2.9
2013	3.1
2014	2.8
2015	3.4
2016	3.6
American Society of Anesthesiologists physical status classification	No. (%)
1	0
2	3 (3)
3	70 (70)
4	27 (27)
5	0
Time for procedure, hours	Mean (SD)
Duration of surgery (incision to closure)	3.9 (28)
Duration in operating room (in room to out of room)	5.4 (3.8)
	Mean (SD)
Fluoroscopy time, minutes	67 (29)
Fluoroscopy dose, mGy	4841 (2941)
Volume of contrast material, mL	78 (34)

SD, Standard deviation.

DISCUSSION

In our series of 100 consecutive patients undergoing endovascular repair of complex aortic aneurysms, the observed perioperative mortality rate was 3% and the incidence of serious adverse events within 30 days of the index procedure was lower than anticipated, given the high-risk population undergoing these extensive repairs. The low rate of paraparesis (1%) and the absence of paralysis observed in this series of patients is encouraging. At 1 year, significant endoleaks occurred at a low rate of 3%, target vessel patency was 92%, and there were no aneurysm ruptures or aneurysm-related mortality. Longer term follow-up is ongoing and key to the critical appraisal of this evolving technology.

In interpreting the rate of spinal cord ischemia, it is important to note that only 36 of the 100 patients were treated for thoracoabdominal aortic aneurysms, of which 17 were type I, II, or III, placing them at significant risk for spinal cord ischemia. This low rate of paraparesis and paralysis may be partially attributed to four factors: (1) as stated before,

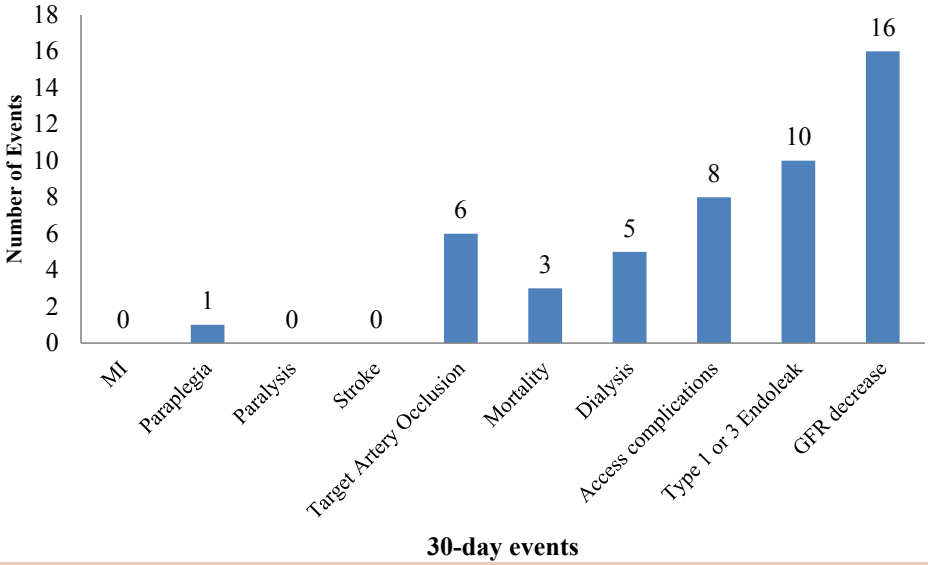

Fig 3. Perioperative events in patients who underwent complex endovascular aneurysm repair (N = 100). *GFR,* Glomerular filtration rate; *MI,* myocardial infarction. Of the 10 type I or type III endoleaks observed within 30 days, 7 resolved after a secondary intervention and 1 resolved without intervention. Of the five patients who required dialysis within 30 days, three resolved and two were permanent.

only 17 patients were treated for type I, II, or II thoracoabdominal aortic aneurysms; (2) endovascular repair is not accompanied by the same ischemia-reperfusion injury associated with open repair; (3) any patient undergoing coverage above the celiac artery was managed according to a standardized lumbar drain and pharmacologic hypertension protocol; and (4) we use a staged approach in which any patient who needs thoracic aortic coverage has the thoracic coverage performed as a first stage, before a second-stage visceral segment and infrarenal aortic or iliac artery treatment. Furthermore, any open surgical adjuncts required (eg, carotid artery-subclavian artery bypass, iliofemoral artery bypass for conduit, or external to internal iliac artery bypass for preservation of internal iliac artery perfusion) are performed as a first stage. This staged strategy has been reported in the past to be associated with reduced rates of paraparesis and paralysis.[26]

The adoption of fenestrated and branched endovascular techniques for complex aortic aneurysms has been substantially slower than that observed for endovascular aneurysm repair, and it has been primarily limited to relatively few centers.[10-16] There are a number of reasons for this limited adoption of complex endovascular aortic aneurysm repair that include but are not limited to restricted access to appropriate devices, a need for sophisticated preoperative and intraoperative imaging, the prerequisite advanced catheter and wire skill set, and a much slower rollout and regulatory approval of company-manufactured devices. In addition, because of the variety of anatomic features that affect device delivery, deployment, and target artery cannulation, the procedural planning is highly complex and requires a substantial knowledge base. Planning includes not only precise measurements but also sound decisions on the type of device, the type of target artery preservation method (scallop, branch, fenestration), the influence that the iliac access will have on the ability to deploy the device, and the optimal sequence of intraoperative steps for deployment. Furthermore, because the incidence of complex aortic disease is significantly less than that of infrarenal aortic aneurysms, it is more difficult to develop and to test these evolving technologies.

Given the relatively high morbidity and mortality associated with the open surgical alternatives to endovascular therapy for complex aortic aneurysms,[4,5,7-9] the development and dissemination of these "next-generation" endovascular technologies remain a significant unmet need. Whereas certain high-volume established centers of excellence for the open management of thoracoabdominal aneurysm are able to achieve acceptable outcomes with perioperative mortality rates in the 7% to 15% range,[6,27-31] most larger statewide and national studies have suggested more sobering outcomes, with elective perioperative mortality rates as high as 22%.[4-9] Our intent in highlighting these published results is not to directly compare our outcomes with those reported in previous series but rather to highlight the relatively high mortality that may potentially be improved on in the future with these new endovascular technologies.

In this context, we believe that the data presented in this study, taken in aggregate with those data published by others with high-volume fenestrated and branched endovascular repair experience,[10-16] suggest that this new technique has evolved to the point at which the outcomes are comparable to those obtained with open repair. Given the relatively recent advent of these

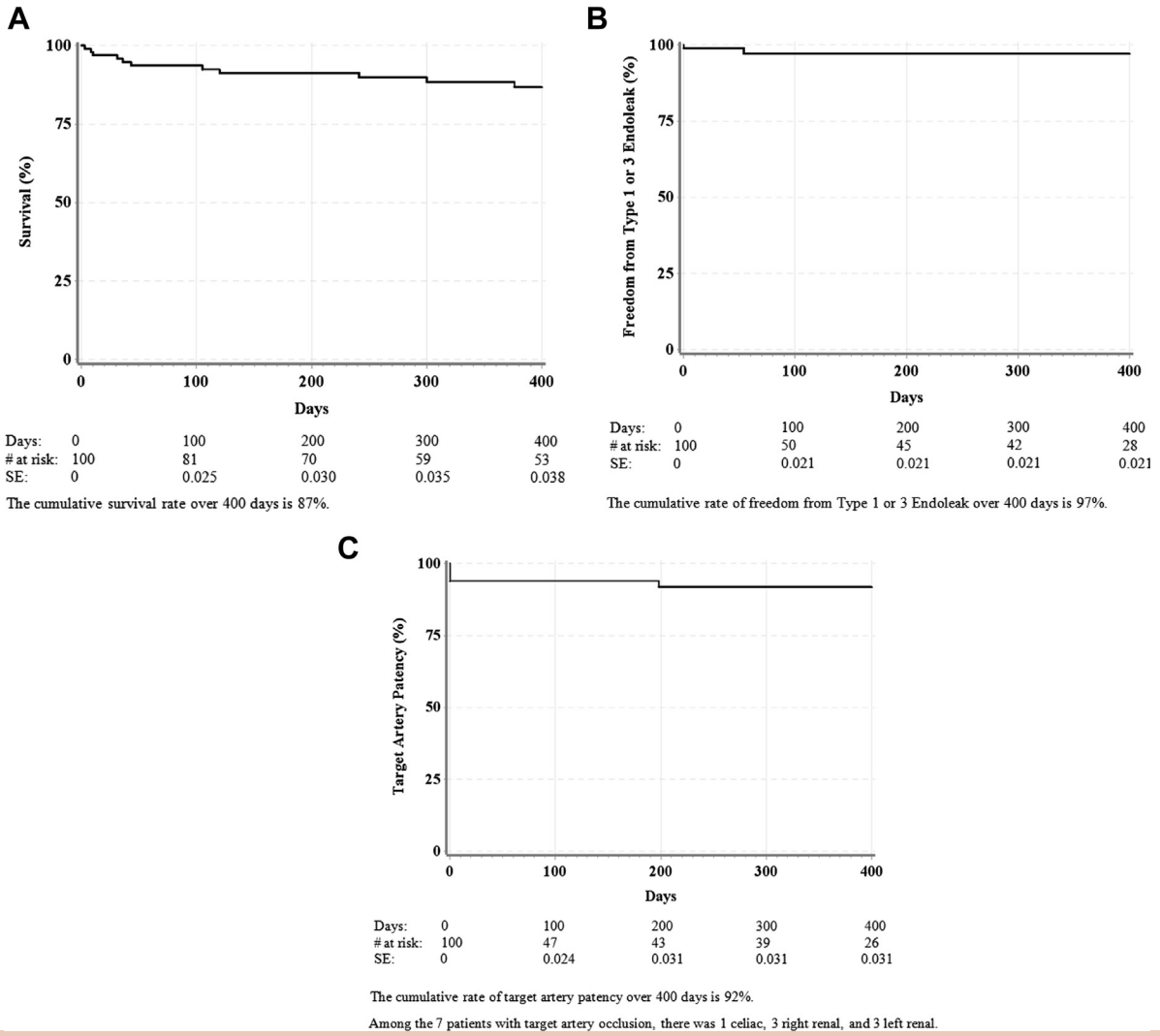

Fig 4. Kaplan-Meier curves demonstrating **(A)** 1-year survival (deaths, n = 11), **(B)** 1-year freedom from type I or type III endoleak (persistent endoleaks, n = 2), and **(C)** 1-year target artery patency (target artery occlusions, n = 7). *SE,* Standard error.

technologies, nearly all of the fenestrated and branched endovascular studies (as is the case with this study) have been limited to patients deemed to be "high risk for open repair." We believe that the data accumulated to date support a shift whereby future studies evaluating the outcomes of fenestrated and branched endovascular repair are performed in clinical trials with expanded indications that include conventional-risk patients.

This series includes all consecutive patients (100%) treated with fenestrated and branched endovascular repair at our center. Whereas one can make a compelling argument that treating a patient with a common iliac artery aneurysm with an iliac artery branch device is different from treating a patient with a thoracoabdominal aortic aneurysm with a four-vessel branch device, we deliberately included all consecutive patients. As a result, the learning curve for using these techniques is accounted for in this report. In this context, the short-term results achieved are encouraging and demonstrate that centers with a focus and commitment to developing a complex endovascular aortic program can be expected to achieve acceptable results.[17] Longer term follow-up is ongoing and necessary to evaluate the durability of these repair strategies.

Fenestrated and branched endograft techniques are not the only minimally invasive strategy for the treatment of complex aortic aneurysms. Parallel endografts (eg, snorkels, periscopes, sandwiches) have been reported as another minimally invasive alternative to open surgical repair for complex aortic aneurysms.[32] The relative durability of parallel endografts compared with fenestrated and branched endografts is yet to be definitively answered. In the setting of urgent or emergent repairs, parallel endografts may provide an

advantage over fenestrated and branched technologies because they can be performed rapidly, with off-the-shelf supplies, in contrast to custom-designed, patient-specific, fenestrated or branched endografts that often require a delay for manufacturing. Use of physician-modified fenestrated endograft techniques can also eliminate the required delay for manufacturing.

There are obvious limitations inherent to this study. Our experience of 100 patients, although large relative to other endovascular series, remains small compared with more mature open surgery series. It would be interesting to know how many patients were evaluated for an endovascular complex aortic repair and turned down for repair. Unfortunately, we have only begun tracking this important metric recently, and we are therefore unable to report our rate of turndown during the study period. Because the program's inception is recent, our duration of follow-up of the patients is limited. Furthermore, this is an extremely heterogeneous group of patients, including a wide spectrum of patients ranging from complex type II thoracoabdominal aneurysms requiring four visceral artery branches to relatively straightforward common iliac artery aneurysms requiring a single internal iliac artery branch. Also, a variety of different endovascular devices were used, including both company-manufactured custom devices and physician-modified devices. This heterogeneity in both anatomy treated and device type used makes any direct comparison with previously published open or endovascular series limited.

Furthermore, our cohort and event rate are presently too small, and our follow-up is too short, to make a meaningful comparative effectiveness evaluation between company-manufactured devices and physician-modified devices. Nonetheless, we do believe that our outcomes are acceptable and justify further investigation through our ongoing physician-sponsored investigational device exemption study. Comparing the durability between company-manufactured devices and physician-modified devices is an important topic that our group is currently evaluating and will be the subject of future study.

CONCLUSIONS

On the basis of this early experience and the published results of several others,[10-16] it is our belief that endovascular technologies will continue to play an increasingly important role in the management of patients with complex aortic aneurysm disease. Because of the complexity of these repairs, the operator's skills required to plan and to perform them, and the institutional support necessary to successfully deliver comprehensive care for these patients, analogous to open thoracoabdominal aortic aneurysm repair, we are likely to see regionalization of endovascular treatment of complex aortic aneurysms to high-volume centers of excellence.

AUTHOR CONTRIBUTIONS

Conception and design: AS, JS, FA, DD, RS, LM
Analysis and interpretation: AS, JS, JF, JD, FA, DD, RS, LM
Data collection: AS, JD
Writing the article: AS, JS, JD, LM
Critical revision of the article: AS, JS, JF, JD, FA, DD, RS, LM
Final approval of the article: AS, JS, JF, JD, FA, DD, RS, LM
Statistical analysis: AS, JF
Obtained funding: AS, LM
Overall responsibility: AS

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Submitted Sep 15, 2016; accepted Dec 13, 2016.

INVITED COMMENTARY

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Endovascular therapies have revolutionized the treatment of aortic diseases, and currently, most patients with aortic aneurysms undergo endovascular aortic aneurysm repair (EVAR). Complex abdominal aortic and thoracoabdominal aortic aneurysms have, however, remained elusive to endovascular repair. Because of the invasive nature of open repair and its associated morbidity and mortality, the search for less invasive treatment modalities remains a priority.

Among several endovascular therapies, fenestrated and branched EVAR has proven to be the safest and most efficacious treatment of complex aortic aneurysms. Limited access to new technologies and devices has thwarted the adoption of advanced endovascular therapies in the United States and other countries, including the use of fenestrated and branched endografts. In addition, the steep learning curve required for these procedures has also been a limiting factor for the widespread adoption of these complex techniques.

Schanzer et al reviewed their initial experience with the use of fenestrated and branched endografts. They report outstanding 30-day morbidity and mortality rates and early technical and clinical success. Their data may, however, be difficult to interpret because they include not only a wide spectrum of aortic diseases treated with fenestrated and branched devices, including juxtarenal, suprarenal, and thoracoabdominal aortic aneurysms, but also an assortment of devices such as the Zenith (Cook Medical, Bloomington, Ind) fenestrated abdominal aortic aneurysm endovascular graft, or ZFEN device, the Zenith p-Branch (Cook Medical) device, physician-modified devices, and premanufactured custom-made devices.