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Endovascular Abdominal Aortic Aneurysm Repair by Interventional Cardiologists—A Community-Based Experience

ABHIJEET BASOOR, M.D.,[1,2] KIRITKUMAR C. PATEL, M.D., F.A.C.C.,[2,3,4] JOHN F. COTANT, M.D., F.A.C.C.,[2] ABDUL R. HALABI, M.D., F.A.C.C.,[2,3,4] MINA TODOROV, M.D.,[5] HAROON CHUGHTAI, M.D.,[2] NISHIT CHOKSI, M.D., F.A.C.C.[2,3,4] BENJAMIN DIACZOK, M.D., F.A.C.P.,[1] SUSAN ZONIA, PH.D.,[6] and MICHELE DEGREGORIO, M.D., F.A.C.C.[2,3,4]

From the [1]Department of Medicine, St. Joseph Mercy Oakland Hospital, Pontiac, Michigan; [2]Division of Cardiology, St. Joseph Mercy Oakland Hospital, Pontiac, Michigan; [3]Interventional Cardiology Unit, Department of Cardiovascular Medicine, William Beaumont Hospital, Royal Oak, Michigan; [4]Division of Cardiology, Detroit Medical Center, Detroit, Michigan; [5]Department of Surgery, St. Joseph Mercy Oakland Hospital, Pontiac, Michigan; and [6]Chair of I.R.B., St. Joseph Mercy Oakland Hospital, Pontiac, Michigan

Introduction: *Endovascular repair of abdominal aortic aneurysm (AAA) is a relatively recent technology. In comparison to the conventional open surgical treatment for AAA, endovascular AAA repair (EVAR) combines a less-invasive approach with lower morbidity and mortality. There have been few studies regarding the performance of this procedure in a community-based setting. We report our experience of EVAR performed primarily by interventional cardiologists in a community hospital.*

Methods: *In our community hospital setting, between September 2005 and November 2007, we included all patients who underwent EVAR by interventional cardiologists, with available on-site vascular surgical support. Clinical and serial computed angiographic imaging outcomes were followed by a retrospective chart review. Data collection tools included demographic and clinical characteristics, anatomical aneurysm features, length of stay, peri- and postprocedural complications, and mortality.*

Results: *A total of 71 consecutive patients had EVAR attempted. The endovascular stent placement was successful in 67 (93%) patients. Thirty-day mortality in this study was 1 of 71 (1.4%). All four procedural failures and the single periprocedural mortality occurred in women. Mean follow-up was 12 months. There were a total of six mortalities and among these four were women ($P \leq 0.001$); however, multivariate analysis revealed loss of significant difference in mortality ($P = 0.16$). Major complications following EVAR were noted in 10 of 71 (14%) patients.*

Conclusion: *EVAR can be successfully performed by experienced interventional cardiologists with vascular surgical support in a community-based setting. In our experience, there is acceptable rate of complications and mortality in a carefully selected patient population.* (J Interven Cardiol 2010;23:485–490)

Introduction

Abdominal aortic aneurysm (AAA) is a condition associated with high mortality and morbidity. Historically, open surgical repair for AAA has been the only available therapy. Recently, endovascular AAA repair (EVAR) has become an increasingly attractive and minimally invasive treatment modality for AAA. The first endovascular treatment of AAA was performed in 1990 and reported by Parodi et al. in 1991.[1] Since Parodi's initial report, numerous studies have shown

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Address for reprints: Abhijeet Basoor, M.D., Medical Education-Department of Cardiology, St. Joseph Mercy Oakland Hospital, 44405 Woodward Avenue, Pontiac, MI 48341. Fax: 248-858-3244; e-mail: drasbasoor@hotmail.com

that endovascular treatment of AAAs can be performed safely.

According to the 2005 American College of Cardiology (ACC)/American Heart Association (AHA) guidelines for AAA, EVAR is a reasonable alternative procedure to open surgery in patients that are at high risk (Class IIa) and at low or average risk for complications (Class IIb). As the results of EVAR-1 trial have shown, endovascular repair, compared to open repair of AAA, offers a clear benefit in terms of reduction in postoperative adverse events and 30-day mortality.[2] Subsequently, other studies have repeatedly demonstrated that endovascular treatment is associated with lower morbidity rates and potentially decreased mortality rates, when compared to open surgical repair.[3–7] Based on a meta-analysis of randomized controlled trials, the operative mortality rate of open repair was 4.7% and that of EVAR was 1.6%.[8] Non-randomized case studies and comparative observational reports showed the incidence of major complications following EVAR to be 19.5% versus 37.5% for open repair.[9]

In most institutions, EVAR is performed by vascular surgeons. Recent developments in transcatheter delivery of vascular prosthetic devices have allowed non-surgical endovascular specialists to use these devices for treatment of a variety of vascular defects. There are few published studies regarding EVAR performed by interventional cardiologists in a community-based setting. We report the outcomes of EVAR on subjects undergoing the procedure in our community hospital, performed by interventional cardiologists with an available on-site vascular surgery support.

Table 1. Inclusion and Exclusion Criteria

General Inclusion Criteria:
1. Age ≥ 18 years old,
2. Informed consent, and
3. Patient to comply with posttreatment follow-up requirements.

Anatomic Inclusion Criteria:
1. Only one of the following four conditions needs to be met:
   a. Aneurysm ≥ 4.0 cm in diameter,
   b. Saccular aneurysm ≥ 3.0 cm in outer diameter,
   c. Aneurysm twice the normal aortic outer diameter, and
   d. Rapidly growing aneurysm (≥5 mm over 6 months).
2. Proximal aortic neck fixation length that is nonaneurismal aorta between the lowest renal artery and the aneurysm ∼15 mm.
3. Nonaneurismal proximal aortic neck diameter 18–26 mm.
4. Minimum internal diameter of the external iliac artery ≥ 7 mm for access.
5. Common iliac artery inner diameter vessel size 10–14 mm for use with 16-mm outer-diameter graft or 14–18 mm with 20-mm outer-diameter graft.

General Exclusion Criteria:
1. Life expectancy < 2 years,
2. Pregnant or lactating woman,
3. Acutely ruptured or leaking aneurysm,
4. Contraindications for nonionic contrast medium or anticoagulation drugs,
5. Coagulopathy or bleeding disorder present, and
6. Active systemic or localized groin infection.

Anatomic Exclusion Criteria:
1. Proximal aortic attachment site ≥60° angle to the body of the aneurysm,
2. Iliac arteries ≥90° angle,
3. ≤15 mm of nonaneurysm common iliac artery above the internal/external iliac bifurcation on both sides, and
4. Thrombus ≥30% at implantation site.

Material and Methods

Approval was obtained by the Institutional Board Review of our hospital for the study. Consecutive patients who underwent EVAR in our community hospital between September 2005 and November 2007 were included in the study. All procedures were performed by cardiologists experienced in percutaneous interventions with vascular surgery support. As per the protocol of our hospital interventional lab, all patients underwent strict screening using the inclusion and exclusion criteria as shown in Table 1.

Data Collection Tools. Data were collected about demographic variables (age, gender, body surface area [BSA], body mass index [BMI], comorbidities, and risk factors), procedural details (type of procedure, size of aneurysm, type of graft used, primary conversion to open repair, procedural success, and periprocedural complications/mortality), and follow-ups (length of hospital stay, endoleaks, secondary conversions, and postprocedural complications/mortality). All patients were followed with serial clinical and computed tomographic angiograms at 1 month, 3–6 months, 1 year, and every year thereafter (as per the follow-up protocol). All the data collection including the follow-up was performed through the retrospective chart review of the hospital and outpatient clinic records.

Definitions. The success rate was defined as successful deployment of the endograft without any AAA-related rupture or death. Primary conversion was defined as EVAR requiring conversion to open surgical repair due to vessel rupture or any other serious complications during or immediately following the endovascular repair. Secondary conversion was open repair of aneurysm after the completion of EVAR. The

periprocedural mortality rate was defined as death related to EVAR within 30 days of the procedure. Aneurysm-related death was defined as death due to aneurysm rupture or aneurysm repair. Complications were defined as periprocedural if they occurred within 30 days and postprocedural if after 30 days of the procedure. Major complications included all of the following: limb or life threatening, ischemic, cardiac, respiratory, renal, neurological, hemorrhagic (requiring the transfusion of $\geq$3 units of blood products), systemic infection, major endoleaks, graft failure, migration, and fistulae formation. In accordance with other published reports, endoleaks were classified as a minor complication if the contrast agent was localized to a local portion of the sac and major if it opacified the whole sac.[10] Data were categorized as primary outcomes (periprocedural mortality and primary conversion) and secondary outcomes (delayed mortality, major and minor complications).

Statistical Analysis. Variables were expressed as continuous or categorical. Independent Student's t-test and chi-square test were used to find the significant differences between the groups. Multiple regressions were used to adjust the association between gender and unsuccessful procedure/mortality for confounding factors (age, gender, hypertension, peripheral vascular disease, dyslipidemia, and BSA). We also calculated the odds ratio for unsuccessful procedure in the presence of each of the above-mentioned variables. Data were analyzed using SPSS version 11 (IBM, Chicago, IL, USA). Unless stated otherwise, data were presented as mean $\pm$ standard deviation; a two-sided P value $\leq$0.05 was considered significant.

Results

Patient Characteristics. Seventy-one patients had EVAR attempted. Baseline and clinical characteristics of the study participants are shown in Table 2. The mean age of the patient population was 73 $\pm$ 8 years, (range 54–89 years) with 33% women. The mean AAA diameter was 4.85 cm (range 4.0–7.4 cm). Three patients had bilateral iliac artery aneurysms, three patients had unilateral iliac artery aneurysms, and three patients had a saccular aneurysm. An aortic proximal cuff was used in 10 patients. Risk factors and comorbidities were more prevalent in women. Specifically, hypertension and dyslipidemia were significantly more prevalent (P = 0.001 and P < 0.0001, respectively) in women compared to men.

Table 2. Baseline Characteristics of the Study Population (Count [%])

	Men	Women	P Value
Age (years)	73	77	0.08
Count	55 (77)	16 (23)	
Coronary artery disease	41 (74)	12 (75)	0.97
Hypertension	28 (51)	13 (81)	0.001
Dyslipidemia	26 (47)	14 (87)	<0.001
Smoking	24 (44)	10 (62)	0.18
Peripheral vascular disease	16 (29)	6 (37)	0.52
Diabetes mellitus	12 (22)	4 (25)	0.78
Chronic kidney disease	10 (18)	5 (31)	0.26
Creatinine (mg/dL)	1.19	1.11	0.40
Congestive heart failure	12 (22)	7 (44)	0.08
Ejection fraction (%)	51	52	
Obesity	14 (25)	6 (37)	0.34
BSA	2.07	1.74	<0.001
BMI	27.57	27.49	0.95
On medications			
Aspirin	37 (67)	12 (75)	0.55
Clopidogrel	20 (36)	9 (56)	0.15
Warfarin	6 (11)	0	0.17

Note: BSA = body surface area; BMI = body mass index.

Success Rate, Type of Stent Used, and Procedure Abandonment Rate. The outcome of all attempted EVARs is shown in Figure 1. The endovascular stent placement was successful in 66 patients (success rate of 93%). Sixty-four patients received an Endologix Powerlink stent (Endologix Inc., Irvine, CA, USA), and two patients received Medtronic AneuRx stent (Medtronic Inc., Santa Rosa, CA, USA). The endovascular stent could not be deployed in 4 patients due to unfavorable vessel anatomy resulting in approximately 6% (4 out

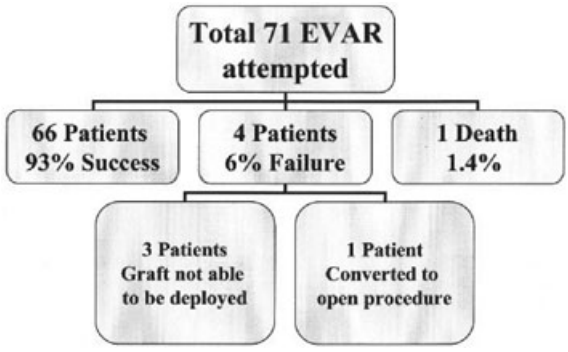

Figure 1. Success and failure rates of EVAR procedure.

Table 3. Characteristics of Patients with Unsuccessful EVAR

	Age (years)	Gender	BSA	BMI	Vascular Anatomic Cause of Failure
1.	83	Female	1.68	30	Tortuosity of the infrarenal aorta (unable to deploy graft)
2.	84	Female	1.76	32	Stenosed and severely calcified right iliac artery (unable to deploy graft)
3.	76	Female	1.75	31	Stenosed bilateral iliac arteries (unable to deploy graft)
4.	81	Female	1.26	16.6	Right iliac and common femoral artery rupture (converted to open procedure)

of 71) abandonment rate. The characteristics of these patients who could not undergo EVAR successfully are shown in Table 3.

Outcomes after EVAR. The mean length of hospital stay for all patients who successfully underwent EVAR was 2.8 days (range 1–17 days). The mean follow-up was 12 months (range 3–29 months). The periprocedural and follow-up outcomes are shown in Table 4. Major periprocedural complications after EVAR were noted in 14% of patients. The complications included limb ischemia requiring surgical intervention in 5 patients, compartment syndrome in 1, ischemic colitis in 1, renal ischemia in 1, and foot drop in 1 patient. Among the endoleaks, localized type II was seen in 6 patients at 1-month follow-up, but it was persistent in only 2 patients during further follow-up. This corresponds to a 66% spontaneous closure rate for type II endoleaks. The other complications included 16 local complications at the percutaneous entry site including pseudoaneurysms, groin hematomas, seromas, and abscess formation. The primary conversion rate in this study was 1.4% (1 out of 71 patients). This patient went into hemorrhagic shock during the procedure due to rupture of the right iliac and common femoral arteries leading to a retroperitoneal hematoma. The endovascular stent was immediately removed, and the procedure was converted to open repair. The periprocedural mortality was 1 of 71 patients (1.4%) due to acute renal failure in a patient who refused hemodialysis. There was no AAA rupture in the study. During the follow-up, 5 additional patients died and the causes of death are shown in Table 5. Aneurysm-related death was seen in 2 patients, a rate of 2.8% per year (one periprocedural and another one during further follow-up). The overall mortality rate was 8% in 1-year average follow-up. Of the 6 deceased patients, 4 were women and 2 men giving a statistically significant difference in mortality ($P \leq 0.001$). However, we performed a multivariate analysis using age, gender, peripheral vascular disease, hypertension, BSA, and dyslipidemia as covariates. We noticed a loss of significant difference in mortality after adjusting for these variables ($P = 0.16$). Similarly, we also performed a multivariate analysis for association of gender with unsuccessful procedures. We noticed a loss of significant difference after adjusting for above-mentioned variables ($P = 0.99$) Table 6.

Table 4. Periprocedural (30 days) and Further Follow-up Complications after EVAR

	Number of Patients	
	Periprocedural	At Further Follow-up (Average at 1 Year)
Major complication		
Limb ischemia	5	None
Compartment syndrome	1	None
Retroperitoneal hematoma	1	None
Ischemic colitis	1	None
Foot drop	1	None
Minor and localized complications		
Endoleak type II	6	2
Pseudoaneurysm	2	2 (small and unchanged)
Groin hematoma	6	None
Abscess	4	None
Seroma	4	None

Discussion

The overall patient mortality rate for ruptured AAA is between 75% and 85%, making it the 13th leading cause of death in the United States. Since its initial description in 1991, EVAR has gained significant popularity and acceptance in the cardiovascular community. Via insertion of a vascular endograft into the lumen of the aneurysm, EVAR excludes the aneurysm from flowing through the aorta thereby minimizing its risk of rupture. Some of the common complications that are specific to the endovascular repair are endoleaks and limb ischemia.[8,9] Endoleak is the presence of persistent flow of blood into the aneurysm

Table 5. Deceased Patients and Their Characteristics

Age (years)	Gender	Cause of Death	Other Comorbidities	Successful EVAR Completed	Time of Death Postprocedure
78	Female	ARF	CAD, CKD, dyslipidemia, DM, HTN, PVD, smoking	No	1 week
81	Female	PE after primary conversion	CAD, CHF, dyslipidemia, HTN, PVD, smoking	No	2 months
71	Male	MI	CAD, HTN, PVD	Yes	4 months
84	Female	Respiratory arrest due to aspiration	CAD, CKD, dyslipidemia, HTN	Yes	9 months
73	Male	PE after hernia repair	CAD, dyslipidemia, HTN, smoking	Yes	12 months
76	Female	Unknown	CAD, CHF, CKD, HTN, obesity	No	16 months

Note: ARF = acute renal failure; CAD = coronary artery disease; CKD = chronic kidney disease; DM = diabetes mellitus; HTN = hypertension; PVD = peripheral vascular disease; CHF = congestive heart failure; PE = pulmonary embolism.

sac after the device placement. Endoleaks have been classified as Types I–V.[11,12] Type II endoleak occurs when there is perigraft flow from collateral vessels. These are the most common endoleaks, affecting up to 56% of patients.[13] They are associated with a low risk of rupture (0.52% in 15 months) and have a high rate (75% in 5 years) of spontaneous closure.[14,15] In this study, the spontaneous closure rate was 66% in 1 year. Limb ischemia occurs as a result of graft limb occlusion, embolization, or common femoral artery thrombosis. In the presented cohort of patients, there were 5 counts of this major complication due to thromboembolism in the limb. In this study, there were no secondary reinterventions required for any of the major complications. Major complications such as other endoleaks (types I, III, and IV), graft migration, structural failure, graft distortion, aortoenteric fistula, or aneurysm rupture were not encountered during the follow-up. This may be attributed to the advancements in graft design as well as operator-dependent insertion technique. Other authors have shown higher complication rates in women due to smaller vessel size compared to men.[16–18] In our sample, all EVAR failures and the one periprocedure death were among women. Women also had a higher procedure abandonment rate. However, after adjustment for confounding factors, we noticed a loss of significant association between women and unsuccessful procedure. After successful deployment of the endograft, none of the patients studied required an open surgical repair. The primary conversion rate was 1.4%, and there was no delayed or secondary conversion to open repair. We feel the most likely reasons for this are careful selection of patients whose aneurysms are amenable to endovascular repair and vigilant iliac angioplasty to facilitate delivery of the stent. This result is encouraging, as most reports cite a surgical conversion rate of 2–20%.[7,19–22] A total of 6 patients died in this study. All these patients were older than 70 years. As shown in Table 5, only 2 patients had aneurysm-related death. Survival at an average of 1-year follow-up was 92%, which is comparable to other studies.[5] In this particular review, the complication rate was lower than in comparable studies. One of the factors responsible for this could be the use of newer generation bifurcating grafts, which are unibodied and usually require unilateral vascular exposure. Further device developments are still needed, as decreasing the size of the delivery system will allow access to the aorta percutaneously.

Table 6. Multivariate Analysis by Using Unsuccessful Procedure As a Dependent Variable

Variable	β	Odds Ratio	p value
Gender	−24.03	0.00	0.99
Age	−0.33	0.96	1.00
PVD	−16.93	0.00	0.99
HTN	−0.86	0.42	1.00
Dyslipidemia	−17.90	0.00	0.99
BSA	80.04	0.00	0.99

Note: PVD = peripheral vascular disease; HTN = hypertension; BSA = body surface area.

Among patients diagnosed with AAA, screening and evaluation is vital in deciding whether or not an endovascular repair is appropriate. In this study, unsuccessful procedures (Table 3) were more likely in older, shorter, and obese women. However, after multivariate analysis, the significance was lost, showing that the difference was due to the higher prevalence of the comorbidities and older age. Small sample size also might be responsible for this finding. It appears that

younger nonobese patients with fewer risk factors are ideal candidates. These may be important considerations in patient selection for EVAR. Future prospective trials are needed in order to get better understanding of the selection criteria. If EVAR is not feasible or if the patient does not meet the current selection criteria, the candidate should be meticulously followed up and monitored for aneurysm growth, as delineated in the guidelines for open repair.

Conclusion

EVAR is an effective minimally invasive procedure, which may be done by interventional cardiologists supported by vascular surgery. It has a high success rate with acceptable risk of complications especially when there is appropriate patient selection, and it is performed by a highly skilled interventional team.

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