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Percutaneous versus Femoral Cutdown Access for Endovascular Aneurysm Repair

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Abstract

Objective—Prior studies suggest that percutaneous access for endovascular abdominal aortic aneurysm repair (pEVAR) offers significant operative and post-operative benefits compared to femoral cutdown (cEVAR). National data on this topic, however, are limited. We compared patient selection and outcomes for elective pEVAR and cEVAR.

Methods—We identified all patients undergoing either pEVAR (bilateral percutaneous access whether successful or not) or cEVAR (at least one planned groin cutdown) for abdominal aortic aneurysms (AAA), from January 2011 to December 2013 in the Targeted Vascular dataset from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database. Emergent cases, ruptures, cases with an iliac conduit, and cases with a preoperative wound infection were excluded. Groups were compared using chi-square test or t-test or the Mann-Whitney test where appropriate.

Results—4112 patients undergoing elective EVAR were identified; 3004 cEVAR (73%) and 1108 pEVAR (27%). Of all EVAR patients 26% had bilateral percutaneous access, 1.0% had attempted percutaneous access converted to cutdown (4% of pEVARs), while the remainder had a planned cutdown, 63.9% bilateral, and 9.1% unilateral.

There were no significant differences in age, gender, aneurysm diameter or prior open abdominal surgery. Patients undergoing cEVAR were less likely to have congestive heart failure (1.5% vs. 2.4%, P=0.04) but more likely to undergo any concomitant procedure during surgery (32% vs. 26%, P<.01) than patients undergoing pEVAR. Postoperatively, pEVAR patients had shorter operative time (mean 135 vs. 152 minutes, P<.01), shorter length of stay (median 1 day vs. 2 days, P<.01), and fewer wound complications (2.1% vs. 1.0%, P=0.02). On multivariable analysis the

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only predictor of percutaneous access failure was performance of any concomitant procedure (OR 2.0, 95% CI 1.0–4.0, P=0.04).

Conclusions—Currently, 1 in 4 patients treated at Targeted Vascular NSQIP centers are getting pEVAR, which is associated with a high success rate, shorter operation time, shorter length of stay, and fewer wound complications compared to cEVAR.

INTRODUCTION

For patients with an anatomically suitable abdominal aortic aneurysm (AAA), endovascular aortic aneurysm repair (EVAR) has become the preferred choice of treatment during the past decade.[1] Percutaneous access (pEVAR) further minimizes invasiveness compared to femoral cutdown access (cEVAR). A recently published American multicenter randomized trial with 151 patients in centers of excellence with one stent graft, reported high success rates in selected pEVAR patients when compared to cEVAR.[2] Several small single center studies using a variety of grafts showed a reduction in total operative time[2–8] and length of hospital stay.[3, 6, 9, 10] Additionally, access-related complication rates were lower with pEVAR compared to cEVAR.[2, 4, 6–12] Despite these promising results, the possibility of publication bias should be considered. Therefore a larger scale study, of contemporary management of AAA comparing pEVAR and cEVAR, is needed to see if the results from the prior RCT and single centers may be generalizable. We analyzed national outcomes of pEVAR and cEVAR for AAA repair. We aimed to analyze patient selection, anatomic variation and outcomes for elective pEVAR and cEVAR.

METHODS

Data Source

We identified all patients undergoing either pEVAR (bilateral percutaneous access whether successful or not) or cEVAR (at least one planned groin cutdown) for abdominal aortic aneurysms (AAA), from January 2011 to December 2013 in the Targeted Vascular dataset from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database. This is a multi-institutional, risk-adjusted database with 83 participating hospitals in the United States, which collects prospective clinical data of patients undergoing vascular surgery. Data are recorded on preoperative, operative and postoperative patient-level variables after the index procedure. All data collection is performed by trained clinical nurse reviewers to ensure quality. These variables being collected were chosen by vascular surgeons and specific to the index operation e.g. AAA diameter, indication for surgery and attempt at percutaneous access. Variables definitions and details of data collection are available on the ASC NSQIP website.[13] NSQIP does not identify the site of surgery in any way thus precluding volume -outcome analyses as well as outcomes comparison between sites. Emergent cases and ruptures were excluded. Cases with an iliac conduit or with a preoperative open or infected wound were also excluded. As this study contained only de-identified data without any protected health information, the study is not considered human research and therefore is not subject to Institutional Review Board approval or patient consent.

Clinical and outcome variables

Data were collected on relevant patient demographics, including gender, age, history of prior abdominal operations, ASA (American Society of Anesthesia) classification, and aneurysm diameter. Intra-operative data were compared, including indication for surgery, anatomical details, graft type and operative time. To rule out the effect of additional interventions on the mean total operation time, we excluded patients who had a concomitant intervention or a fenestrated graft for the analyses of operative time.

Post-operative outcomes were also compared, including death, rupture, bleeding requiring transfusion, reintubation, return to the operating room, surgical site infections (SSI), any wound complications and overall length of stay. Multivariable logistic regression was used to determine independent predictors of percutaneous access failure, adjusted for potential confounders. Multivariable logistic and linear regressions were used to identify predictors of operative time and length of stay. Additionally, we compared patients with attempted pEVAR converted to cutdown to those with successful pEVAR to identify possible associations with failure. To check for homogeneity within cEVAR group we compared the patients with bilateral groin cutdown to one groin cutdown within the cEVAR cohort.

For obesity we used the cutoff BMI>30 kg/m2. Any wound complication includes wound dehiscence and superficial, deep and organ space surgical site infection (SSI).

Statistical analyses

Categorical variables were compared using chi-square test and continuous variables were compared using the Student t-test or the Mann-Whitney test where appropriate. Statistical significance was defined as $P<0.05$. All statistical analyses were performed using SPSS statistical software (version 20; IBM Corp, Armonk, NY).

RESULTS

We identified a total of 4479 patients who underwent elective EVAR, of which 4112 patients remained after excluding iliac conduits (N=367, 8.2%) and prior wound infections (N=39, 0.9%). There were 3004 (73%) cEVAR and 1108 (27%) pEVAR patients. Of all cEVAR patients 88% had bilateral groin cutdown and 12% had unilateral groin cutdown. Of all pEVAR patients, 96.% had a successful bilateral percutaneous access and 4% had attempted percutaneous access converted to cutdown. pEVAR was performed in 20% in 2011, 27% in 2012, and 29% in 2013. The majority of procedures were performed by vascular surgeons (98% of total patients).

Baseline characteristics

Gender, age, aneurysm diameter and prior open abdominal surgery were similar for both access types. (Table I.) There was a significant difference in race/ethnicity between the two groups, most likely due to more Asian and less white patients in the pEVAR group. More patients with congestive heart failure (2.4% vs. 1.5%, P=0.04) were seen in the pEVAR group.

Outcomes

Patients undergoing cEVAR had more concomitant procedures (32% vs. 26%, P<.01), however, hypogastric embolizations (7.6% vs. 5.8%, P=0.04) were more common in patients with pEVAR (Table II). Between groups, there were no differences in the indication for surgery, the proximal extent of the aneurysm, or the rate of acute conversion to open repair. The distal extent of the aneurysm, however, was more likely to be common or external iliac in the pEVAR group (P<.01).

There were differences in main body device used between cohorts (P<.01), with slightly more Gore Excluder and Endologix Powerlink used in the pEVAR group and slightly more Cook Zenith and Medtronic Endurant use in the cEVAR group. The mean time of operation was shorter for pEVAR (135 min vs. 152 min, P<.01). After exclusion of any cases with concomitant interventions and fenestrated cases the mean total operation time remained significantly shorter (123 min vs. 141 min, P<.01) for pEVAR.

Postoperatively there were more wound complications in patients undergoing cEVAR (2.1% vs. 1.0%, P=0.02), primarily superficial surgical site infection (2% vs. 1%, P=0.03). There were no other significant differences in post-operative complications (Table III). In pEVAR patients the median length of stay was significantly shorter (1 day vs. 2 days, P<.01). The proportion of patients with a length of stay longer than 2 days was significantly lower with pEVAR (46% vs. 56%, P<.01). After correcting for differences in age, race, Chronic Obstructive Pulmonary Disease (COPD), CHF, obesity and concomitant procedures, cutdown was still associated with a significantly longer operative time (16 minutes) and a 39% greater likelihood of length of stay > 2 days.

Comparing single groin cEVAR to bilateral groin cEVAR, we found no differences in postoperative results, other than more deep venous thrombosis (1.1% vs. 0.3%, P=0.03) in the unilateral cutdown cohort. Therefore we combined them in the cEVAR group for all analyses.

The failed percutaneous access patients (N=40, 4%) showed no differences in baseline characteristics when compared to patients with successful pEVAR. Peri-operatively, however, failed pEVAR patients had more acute conversions to open repair (10% vs. 0.2%), more concomitant procedures particularly aortic stenting (13% vs. 0.8%) and lower extremity revascularization (9.4% vs. 1.8%), and as expected longer operative times (Table IV). The only multivariable predictor of percutaneous access failure was performance of any concomitant procedure (OR 2.0, 95% CI 1.0–4.0, P=0.04). After adjustment, age, CHF, COPD and obesity were not predictive of percutaneous access failure.

DISCUSSION

The use of pEVAR in the Targeted Vascular ACS NSQIP increased over the study period. Our main findings in this study of the Targeted Vascular ACS NSQIP database are a technical success rate of 96% in pEVAR patients, a significantly shorter total operation time, a shorter length of hospital stay, and fewer wound complications in patients who were treated with pEVAR.

A recently published multi-center randomized controlled trial by Nelson et al, randomized 151 patients undergoing EVAR with the Endologix device to pEVAR, using either the Prostar XL or Perclose Proglide, versus standard cEVAR.[2] Their study demonstrated a technical success rate of 96% with the use of Perclose Proglide, which was the same as our finding. A lower success rate was seen with the Prostar XL (90%). Unfortunately, we cannot tell which closure device was used in the NSQIP centers. Additionally, Nelson et al also reported significantly shorter operative time for both closure devices and a shorter length of hospital stay for pEVAR compared to cEVAR, which again was confirmed in our analysis suggesting that the results of the randomized trial are generalizable to a broader population of patients and centers using a variety of stentgrafts. The Targeted Vascular ACS NSQIP includes data from a smaller subset of the total NSQIP group of hospitals (83 of 435). This is likely a subset of hospitals with a volume of vascular procedures high enough and a commitment to quality improvement strong enough to warrant participation in this new quality improvement effort at its initiation. Therefore, it seems likely that these data may not be generalizable to all patients undergoing EVAR at all institutions by all providers.

Our previous study reported a success rate of 96% in our single center experience with ultrasound scan-guided pEVAR,[8] and noted an increasing success rate over time with the increased use of ultrasound scan-guided pEVAR. We found that patients with smaller access vessel diameters were more prone to have percutaneous failure. Additionally, a shorter operative time and fewer wound complications in pEVAR patients were found. Among prior published reports we found success rates for pEVAR varying from 71% to 100%.[2–12, 14–16] In addition to access vessel diameter and type of closures device, femoral artery calcification, access vessel tortuousity and groin scars have all been associated with pEVAR failure.[8, 17, 18] Unfortunately, this database does not provide anatomic information about femoral artery calcification, access vessel diameter and previous groin operations. However, our study demonstrates that performing a concomitant procedure is a predictor of percutaneous access failure. A significantly decreased mean total operative time[2–8] and a shorter length of hospital stay[3, 6, 9, 10] were noted in many previous studies in pEVAR patients when compared to cEVAR patients. Prior studies have noted wound complications ranging from 0–11%[9, 14] with a rate of 5.0%[2] noted in the randomized trial. In this analysis of NSQIP centers we found a significantly lower rate of wound complications in pEVAR patients. It may be expected that in the context of a randomized trial minor wound complications may be more likely to be noted compared to retrospective single center studies,[19] however, trained NSQIP nurse clinical reviewers ability to detect surgical site infection has been previously demonstrated.[20] Intraoperative blood loss was noted to be less with pEVAR in one report[11], while other studies report similar blood loss for both groups[6, 7]. Our study shows that the need for intra- and postoperative transfusion is similar in both groups.

Although not significant, we found more obese patients among our cEVAR cohort. It may be that surgeons find percutaneous access more difficult in obese patients. Previous studies showed conflicting results regarding the influence of obesity on pEVAR success rates. Some studies suggest an association between obesity and technical failure of pEVAR [4, 7, 18, 22], while others found that obesity had no influence on the pEVAR success rate[8, 12, 14, 17]. In particular, those studies employing routine use of ultrasound scan-guided pEVAR were

more likely to note the lack of association of obesity with success[8, 16, 23]. Given the increased incidence of wound complications in obese patients, these patients could potentially benefit most from pEVAR,[24] This study has several limitations, which should be noted. With the use of the Targeted Vascular NSQIP database our study design was retrospective and the cohorts were not randomized. Due to the lack of randomization, surgeon's preference and experience likely played a roll in the choice of treatment. We had no data on how patients were selected for pEVAR and we were unable to determine when ultrasound guidance was used, which has been suggested to reduce access related complications.[8, 25] We do not have data describing the type of vascular closure devices that were used. Additionally, the database does not provide information on long-term follow-up and prevented us from comparing the incidence of ileo-femoral stenosis.

CONCLUSION

This study demonstrates that with the use of pEVAR in elective AAA patients, high technical success rates, shorter operation time, shorter length of hospital stay, and fewer wound complications can be achieved.. Our study confirms the findings of the earlier randomized trial and single center studies, highlighting the current state of EVAR in centers that are represented in the Targeted Vascular ACS NSQIP database.

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Table I

Baseline Characteristics of Patients with Abdominal Aortic Aneurysms undergoing EVAR (Percutaneous vs. Cutdown)

Variable	Percutaneous (n=1108)	Cutdown (n=3004)	P Value	Total Cohort (n=4112)
Male gender	81%	81%	0.10	82%
Race or ethnic group *			<.01	
Other/Unknown	5.1%	6.8%		6.3%
White	84%	87%		86%
Black	7.0%	4.1%		4.9%
American Indian/Alaska Native	0%	0.1%		0.1%
Native Hawaiian/Pacific Islander	0.2%	0%		0.1%
Asian	4.2%	1.7%		2.4%
Age (mean)	74	74	0.08	74.1
Age Category (years)			0.10	
18–59	6.1%	5.1%		5.3%
60–69	25%	23%		23%
70–79	42%	42%		42%
80–89	25%	29%		28%
90+	1.7%	1.5%		1.6%
Prior Open Abdominal Surgery	22%	25%	0.07	24%
ASA 4 Classification	21%	22%	0.23	22%
Aneurysm diameter (cm)	5.7	5.7	0.82	5.7
Coexisting conditions				
Congestive heart failure	2.4%	1.5%	0.04	1.8%
Hypertension	81%	81%	0.74	81%
Diabetes	16%	16%	0.82	16%
History of severe COPD	16%	19%	0.08	18%
Dialysis (pre-op)	1.4%	1.2%	0.47	1.2%
Obesity	30%	33%	0.07	32%

Table II

Intra-operative Outcomes of Patients with Abdominal Aortic Aneurysm undergoing EVAR (percutaneous vs. cutdown)

Outcomes	Percutaneous (n=1108)	Cutdown (n=3004)	P Value	Total Cohort (n=4112)
Acute conversion to open AAA repair	0.5%	0.4%	0.56	0.4%
Cutdown access				
Attempted percutaneous access converted to cutdown	3.6%			1%
Bilateral groin cutdown		88%		64%
One groin cutdown		12%		9%
Percutaneous Bilateral	96%			26%
Indication for surgery			0.09	
Diameter	88%	86%		87%
Dissection	0.2%	0.2%		0.2%
Embolization	0.3%	0.6%		0.5%
Non-ruptured symptomatic	4.1%	6.0%		5.5%
Prior endovascular intervention w/ unsatisfactory result	3.5%	2.5%		2.7%
Prior open intervention w/ unsatisfactory result	0.3%	0.5%		0.4%
Rupture with or without hypotension	0.6%	1.7%		1.7%
Thrombosis	0.6%	1.7%		1.7%
Not documented	1.5%	2.3%		2.1%
Main Body Device			<.01	
Cook Zenith	16%	21%		20%
Cook Zenith Fenestrated	1.2%	2.9%		2.4%
Cook Zenith Renu	0.5%	1.3%		1.1%
Endologix Powerlink	9.8%	6.1%		7.1%
Gore Excluder	35%	32%		33%
Lombard Aorfix	0%	0.1%		0%
Medtronic AnueRx	0.4%	0.2%		0.2%
Medtronic Endurant	27%	31%		30%
Medtronic TALENT	0.1%	0.6%		0.5%
Not documented	0.7%	1.2%		1.1%
Other	7.9%	3.0%		4.3%
Trivascular Ovation	1.7%	0.7%		1.0%
Aneurysm Extent			0.07	
Infrarenal	85%	84%		84%
Juxtarenal	3.4%	4.8%		4.4%
Pararenal	2.0%	1.5%		1.6%
Suprarenal	3.8%	2.9%		3.1%
Type IV	0.4%	0.5%		0.5%
Not documented	5.3%	6.4%		6.3%

Outcomes	Percutaneous (n=1108)	Cutdown (n=3004)	P Value	Total Cohort (n=4112)
Distal Aneurysm Extent			<.01	
Aortic	37%	38%		38%
Common Iliac	37%	33%		34%
External Iliac	5.2%	5.0%		5.1%
Internal Iliac	5.0%	8.0%		7.2%
Not documented	17%	16%		16%
Mean OR time (min)	135	152	<.01	148
Median OR time (min)	117	137	<.01	132
Mean OR time (all concomitant procedures excluded)	123	140	<.01	136
Median OR time (all concomitant procedures excluded)	111	128	<.01	122
Renal Stent	5.9%	7.1%	0.17	6.8%
Hypogastric Embolization	7.6%	5.8%	0.04	6.3%
Hypogastric Revascularization	3.2%	4.6%	0.05	4.2%
Lower Extremity Revascularization	2.0%	4.7%	<.01	3.9%
Iliac Branched Device	11%	14%	0.01	13%
Aortic (Bare metal) Stent	1.3%	2.5%	0.02	2.1%
Iliac (Bare metal) Stent	3.4%	3.4%	0.92	3.4%
Any Concomitant Procedure	26%	32%	<.01	30%

Table III

Post-operative Outcomes of Patients with Abdominal Aortic Aneurysms undergoing EVAR (percutaneous vs. cutdown)

Outcomes	Percutaneous (n=1108)	Cutdown (n=3004)	P Value
Death at 30 days (% of patients)	1.7%	1.4%	0.51
Death in hospital	1.1%	0.6%	0.14
Rupture	0.3%	0.1%	0.10
Medical complications (% of patients)			
Myocardial Infarction	0.7%	1.3%	0.12
Cardiac Arrest requiring CPR	0.5%	0.5%	0.76
Pneumonia	0.8%	0.7%	0.62
Pulmonary Embolism	0.2%	0.2%	0.75
Progressive Renal Insufficiency	0.1%	0.4%	0.09
Acute Renal Failure	0.4%	0.5%	0.56
Urinary Tract Infection	1.2%	1.3%	0.81
Stroke	0.1%	0.4%	0.15
Deep Vein Thrombosis	0.9%	0.4%	0.05
Transfusion	9.3%	10.9%	0.13
Sepsis	0.4%	0.5%	0.56
Surgical complications (% of patients)			
Prolonged Intubation (> 48 hours)	0.8%	0.8%	0.88
Reintubation	1.4%	1.3%	0.65
Return to OR	3.4%	4.0%	0.43
Ischeamic colitis	0.5%	0.4%	0.65
Lower Extremity Ischemia	1.6%	1.2%	0.25
Any Wound Complication	1.0%	2.1%	0.02
Wound dehiscence	0%	0.1%	0.22
Surgical Site Infection	1.0%	2.0%	0.03
Mean length of hospital stay (no. of days)	2.8	3.0	0.48
Median length of hospital stay (no. of days)	1	2	<.01
LOS > 2 days	26%	32%	<.01
LOS > 1 day	46%	56%	<.01
Discharged home	93%	93%	0.52

Table IV

Baseline Characteristics of Patients with Abdominal Aortic Aneurysms undergoing EVAR (Percutaneous failure vs. percutaneous bilateral access)

Variable	Percutaneous failed (N=40)	Percutaneous (N=1068)	P Value
Male gender	73%	84%	0.08
White race	83%	84%	0.83
Age (mean)	75.3	73.7	0.25
Prior Open Abdominal Surgery	31%	22%	0.24
ASA 4 Classification	20%	21%	1.00
Aneurysm diameter (cm)	5.7	5.7	0.99
Coexisting conditions			
Congestive heart failure	2.5%	2.4%	1.00
Hypertension	85%	80%	0.55
Diabetes	5.0%	16%	0.07
Chronic Obstructive Pulmonary Disease	20%	16%	0.52
Dialysis (pre-op)	5.0%	1.3%	0.11
Obesity	23%	30%	0.48
Acute conversion to open AAA repair	10%	0.2%	<.01
Mean OR time (min)	219	131	<.01
Median OR time (min)	195	116	<.01
Mean OR time (all concomitant procedures excluded)	207	121	<.01
Median OR time (all concomitant procedures excluded)	191	110	<.01
Renal Stent	7.5%	5.8%	0.51
Hypogastric Embolization	5.0%	7.7%	0.76
Hypogastric Revascularization	5.0%	3.1%	0.36
Lower Extremity Revascularization	9.4%	1.8%	0.02
Iliac Branched Device	18%	10%	0.18
Aortic (Bare metal) Stent	13%	0.8%	<.01
Iliac (Bare metal) Stent	7.5%	3.3%	0.15
Any Concomitant Procedure	38%	26%	0.10