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Costs Attributable to Arteriovenous Fistula and Arteriovenous Graft Placements in Hemodialysis Patients with Medicare coverage

Robert J. Nordyke[a] Heidi Reichert[b] Lauren C. Bylsma[b] Jenny J. Jackson[c] Shawn M. Gage[c, d] Jon Fryzek[b] Prabir Roy-Chaudhury[e, f] Theodore Lithgow[c]

[a]Beta6 Consulting Group, Los Angeles, CA, USA; [b]EpidStrategies, Katy, TX, USA; [c]Humacyte, Incorporated, Durham, NC, USA; [d]Department of Surgery, Duke University, Durham, NC, USA; [e]Division of Nephrology, University of North Carolina, Chapel Hill, NC, USA; [f]University of North Carolina Kidney Center, Chapel Hill, NC, USA

Keywords

Vascular access · Hemodialysis · Healthcare costs · Health economics · Arteriovenous fistula · Arteriovenous graft

Abstract

Introduction: Hemodialysis (HD) in end-stage renal disease (ESRD) patients requires vascular access (VA) through an arteriovenous fistula (AVF), a prosthetic arteriovenous graft (AVG), or a central venous catheter. While AVF or AVG is commonly used for HD, the economic implications of AVF versus AVG use have not been fully established. We describe the healthcare resource utilization and costs of AVF and AVG use for incident ESRD patients in the United States. ***Methods:*** This observational cohort study of AVF and AVG placements used data from the United States Renal Data System to identify and follow access placements. AVF and AVG placements after ESRD onset for incident patients from 2012 to 2014 with continuous Medicare primary coverage were included. All-cause and access-related Medicare costs were averaged over the placement lifetime and expressed as per dialysis-month costs. ***Results:*** The analysis included 38,035 AVF placements and 12,789 AVG placements. Total all-cause monthly costs for AVF averaged USD 8,508; mean monthly costs were USD 3,027 for inpatient (IP), USD 3,139 for outpatient (OP), USD 1,572 for physician services, and USD 770 for other care settings. Access-related monthly costs averaged USD 1,699 and represented 20% of all-cause charges for AVFs. Mean all-cause monthly costs for AVG were USD 9,605; by setting monthly costs were USD 3,811 for IP, USD 3,034 for OP, USD 1,881 for physician services and USD 879 for other care settings. Access-related monthly costs averaged USD 2,656 and represented 28% of all-cause charges for AVGs. ***Discussion/Conclusions:*** This study indicates that costs due to VA are a significant burden on Medicare budgets and on patients. The factors driving access-related utilization and costs merit attention in future research. Both optimizing process of care and discovery innovation may significantly accelerate better stewardship of available healthcare resources.

Introduction

Vascular access (VA) is critical to hemodialysis (HD) in end-stage renal disease (ESRD) and is central to patient functioning and quality of life. The type of VA is also a key driver of clinical events, particularly infections and thromboses, and consequent resource utilization and costs [1–8]. In response to reported lower rates of morbidity and mortality with arteriovenous fistulae (AVF) versus central venous catheters (CVC), yet relatively low utilization of AVF,

KARGER

E-Mail karger@karger.com
www.karger.com/ajn

Theodore Lithgow
Humacyte, Incorporated
2525 E NC Highway 54, Durham, NC 27713 (USA)
E-Mail lithgow@humacyte.com

the Fistula First initiative was launched by the Centers for Medicare and Medicaid Services in 2003. Since that time CVC use among prevalent HD patients has declined substantially; in 2016, 79% of patients were using an AVF or arteriovenous graft (AVG) without a catheter, 1 year after initiating HD [5]. While overall morbidity and mortality associated with VA may be on the decline, the economic implications of AVF versus AVG use have not been fully characterized. AVFs may require more interventions post-placement to achieve maturation and maintain patency, but may have more long-term savings than AVGs [1, 2]. Several approaches have been implemented to better understand the economic implications of VA in HD.

The 2010 Annual Data Report (ADR) from the United States Renal Data System (USRDS) reported on costs by VA type [6]. Patients were classified into cohorts based on access type and costs were tracked forward for 1 year. Access event costs (per patient per year) were found to be highest among patients with an AVG (USD 8,683), followed by patients on CVC (USD 6,402), and patients on AVF (USD 3,480). Total annual costs for HD patients were lowest for AVFs (USD 59,792) followed by AVG (USD 73,081) and CVC (USD 79,890, all 2010 dollars).

Costs related to VA have recently received more attention [7, 8]. In an analysis of the USRDS claims data, Thamer et al. [8] examined the impact of patency and nonuse on VA-related costs among patients using an AVF. Also using patient-level analyses, AVF patients were classified into 3 cohorts based on access type used at initiation of HD: (1) a mature AVF; (2) a CVC with a maturing AVF; or (3) CVC only with a later AVF placement. Patients were followed for up to 2.5 years. VA-related costs were identified using a defined list of procedures, which were then stratified by patency outcomes in year 1. Across all 3 patient cohorts, patients who maintained primary patency during year 1 experienced the lowest VA-related costs, with increasing costs for loss of primary patency, loss of secondary patency, and AVF nonuse.

These analyses have clearly demonstrated the substantial economic burden related to VA in HD. The choice of placing a specific access type, however, is complex and dependent on patient demographics and clinical characteristics, physician behaviors, process of care pathways, and other health system factors [9], few of which are observed in an administrative claims dataset. Moreover, the specific type of VA may change over timeframes shorter than 1 year.

Our aim in this study was to evaluate the utilization and costs (VA-specific and all-cause) related to AVF and AVG placements using the placements themselves as the unit of analysis. By attributing events and costs to the access type actually used, our analysis aims to more clearly distinguish the true cost implications of a particular type of VA in a real-world setting.

Materials and Methods

Inclusion Criteria

Our cohort included all AVF and AVG placements for incident ESRD patients with continuous Medicare primary coverage as of first ESRD service between January 1, 2012, and June 30, 2014. Patients were required to have CROWNWeb reporting over the study period to identify access use. We only included incident ESRD patients with continuous Medicare primary coverage in order to have a complete history of treatment costs over the study period. Exclusion counts are shown in the study cohort flow diagram (online suppl. Fig. 1; for all online suppl. material, see www.karger.com/doi/10.1159/000502507).

Placements

Placements were identified using Healthcare Common Procedure Coding System codes 36818 – 36821 and 36825 for AVF and code 36830 for AVG. Accesses placed with codes 36825 and 36830 simultaneously were considered AVG. Additional access identification methods are further described elsewhere [10]. Placement of a new AVF or AVG access marked the start of an access lifetime. Access abandonment occurred at subsequent placement, transplantation, kidney function recovery, loss to follow-up, transition to non-HD renal replacement therapy, death, or end of study period (December 31, 2014). Dialysis months for each access were calculated as the number of months from access placement to abandonment, regardless of whether the placement was ever used for dialysis.

Outcomes

Healthcare utilization and claim payment amounts were attributed to the access in place at the time of service, for physician services, inpatient (IP) facility visits, outpatient (OP) facility visits, and treatment in other (skilled nursing, home health, and hospice) settings. Total utilization and costs for the access, including costs associated with CVC placement and use, were then averaged over the dialysis-month time. All-cause utilization and costs incorporated claims for all services, while VA-related utilization and costs included only claims with a diagnosis or procedure code predefined by a panel of clinician and coding specialists to be related to VA management (online suppl. Table S1). Access lifetime cost trends were captured in 6 month increments by averaging costs incurred during each 6-month period for the accesses surviving until the endpoint (6, 12, 18, and 24 months). All costs were adjusted to 2017 US Dollars.

Drugs covered under the ESRD Prospective Payment System (PPS, online suppl. Table S2) over the observation period were identified in claims and attributed to the access in place at the time of administration. Total utilization was averaged over the access dialysis-months. Drug cost data were not available since in-clinic drugs are bundled in the ESRD PPS.

Finally, catheter use for dialysis was identified using CROWNWeb reports. All monthly reports indicating dialysis via catheter were associated with the arteriovenous access in place at the time.

The total reports of catheter use per access divided by the access dialysis-months yielded proportion of access months requiring some catheter use.

Statistical Analyses

Statistical comparisons between the AVF and AVG placement groups included 2-sample proportion tests for binary measures, *t* tests, and nonparametric Wilcoxon tests for continuous measures. Alpha was set to 0.001 to account for sample size. Analyses were performed using Stata (version 15) [11]. This study was exempt from Institutional Review Board review in accordance with 45 CFR 46.101(b; 4) as the data were previously collected, and patients were deidentified before receipt of data.

Results

Over the 3-year study period 2012–2014, a total of 50,824 AVF or AVG placements and 41,779 unique patients were included (Table 1). The majority of patients had just one AVF or AVG placement, though 13% of the patients with an initial AVF placement had a second or greater placement and 10% of patients with an initial AVG had multiple placements. The mean number of subsequent placements (following the initial placement of an AVF or AVG) was 0.23 for patients with an initial AVF placement and 0.18 for AVGs ($p < 0.001$). There were 2,895 (6.9%) unique patients who had at least 1 of each AVF and AVG. Reflecting current practice patterns, catheters were the predominant access used at the first maintenance dialysis session. Both ESRD vintage at the end of the study and ESRD cause were comparable between AVF and AVG placements, with diabetes and hypertension accounting for >80% of patients. However, patient characteristics did differ between AVF and AVG placements in terms of gender and race/ethnicity.

Access-related costs comprised a substantial percentage of total costs for each access type (Table 2). Access costs were 22–31% of IP costs (AVF-AVG), 21–31% of OP costs, and 24–28% of Physician Services. Access-related costs accounted for a negligible portion of other (SNF, Home Health, Hospice, DME) costs. Overall, access-related costs were 20–28% of total costs. Access-related costs, excluding dialysis services, were 27–35% of total costs. Access-related costs for AVGs were substantially greater than those for AVFs, with IP costs for AVGs 79% higher than AVF, OP costs were 41% higher, and physician services costs 42% higher. These cost differences were driven in part by higher utilization intensity in AVGs: IP admissions and length of stay were slightly higher for AVGs; access-related OP visits were slightly higher; and the number of physician service encounters was slightly higher. Taken together, access-related utilization also placed a burden on patients, with VA events representing about 12–17% of IP admissions and 36–43% of nondialysis session OP visits. Overall, total access-related costs of AVGs were 56% higher than AVFs. Due to the large number of placements in our sample, nearly all differences between the AVF and AVG placement groups were found to be significant (Table 2).

Trends in mean all-cause costs per dialysis-month over the access life cycle are shown in Figure 1 for AVFs and AVGs. The trends in all-cause costs declined over time, with the highest levels of utilization occurring within 6 months of a placement and stabilizing after 12 months post-placement. AVG costs followed a similar pattern but were consistently greater than AVFs. Time trends in mean access-related costs per dialysis-month also demonstrated a similar decline over the access lifecycle (Fig. 2). Access-related costs for AVFs decreased 55% from the first time period (months 1–6) to the second period (7–12 months) and decreased an additional 27% from months 7–12 to 13–18 months post-placement. Time trends in mean access-related costs for AVGs followed a similar pattern with higher overall cost levels. For AVFs, access-related IP costs consistently represented approximately one-third (33–38%) of per-month VA costs over the access life in this study period, while the range was slightly higher for AVGs (38–45%).

Utilization of drugs under the ESRD PPS (online suppl. Table S3) was clinically comparable for patients with AVFs compared to those with AVGs in the other access management and antiinfectives categories. However, percent of cohort ever using plasminogen activators was slightly higher for AVGs (11.0 vs. 7.3% AVF), while percent of cohort ever using erythropoiesis-stimulation agents and other anemia management drugs were slightly greater for AVFs (91.4 vs. 88.6% erythropoiesis-stimulation agent AVF vs. AVG, 91.2 vs. 85.8% other anemia management drugs AVF vs. AVG).

CVC use among patients with either AVFs or AVGs was substantial and significantly different between groups (online suppl. Table S4). CVC use was reported in CROWNWeb for 72% of AVF placements but only for 23% of AVG placements. This difference is due to the far shorter maturation times for AVGs versus AVFs which, given the once per month data collection, results in few mentions of CVC use in the first month post-placement in CROWNWeb for AVGs. Despite this difference, the proportion of placements dialyzing with a CVC at least once per month over the life of the arteriovenous access was more comparable at 50% (AVGs) and 58% (AVFs).

Table 1. Characteristics of ESRD patients (indexed 2012–2014) with continuous medicare coverage as primary payer and 1 or more AVF or AVG placements at any time after the onset of ESRD

	AVFs	AVGs
Patients[a, b]	33,091	11,583
Placements	38,035	12,789
Median placements per patient after onset of ESRD (range)	1 (1–7)	1 (1–6)
Patients with one placement, *n* (%)	28,663 (87)	10,494 (91)
Patients with 2 or more placements, *n* (%)	4,428 (13)	1,089 (9)
Access used at first maintenance dialysis, *n* (%)		
Fistula	988 (3)	564 (5)
Graft	307 (1)	344 (3)
Catheter	30,803 (93)	10,417 (90)
Other/missing	993 (3)	258 (2)
Gender, *n* (%)		
Male	18,814 (57)	5,044 (44)
Female	14,277 (43)	6,539 (56)
Age at first ESRD service, *n* (%)	69.0 (12.2)	70.5 (12.2)
Years with ESRD as of end of 2014, *n* (%)		
≤1	4,224 (13)	1,233 (11)
1–2	13,918 (42)	4,700 (41)
2–3	14,949 (45)	5,650 (49)
Race, *n* (%)		
White	23,857 (72)	7,059 (61)
Black	7,670 (23)	4,004 (35)
Asian	1,168 (4)	455 (4)
Native American	364 (1)	56 (0)
Other	32 (<1)	*n* < 11*
Hispanic ethnicity, *n* (%)	3,970 (12)	1,185 (10)
Received a transplant, *n* (%)	586 (2)	140 (1)
Comorbidities, *n* (%)		
Smoking/tobacco use	1,963 (6)	613 (5)
Obesity	13,368 (40)	4,435 (38)
Diabetes	20,105 (61)	6,971 (60)
Cardiovascular disease	14,716 (44)	5,047 (44)
Hypertension	29,241 (88)	10,252 (89)
Cancer	2,761 (8)	969 (8)
Primary disease causing ESRD, *n* (%)		
Diabetes	16,350 (49)	5,545 (48)
Hypertension	10,521 (32)	3,975 (34)
Glomerulonephritis	1,573 (5)	544 (5)
Cystic kidney disease	297 (1)	107 (1)
Other/unknown	4,325 (13)	1,401 (12)

[a] All patients with first ESRD service date between January 1, 2012 and June 30, 2014 that have continuous coverage with medicare as primary payer as of first ESRD-related service, and also have one or more AVF or AVG placed after onset of ESRD over the study period.
[b] Patient $n = 41,779$. Since $n = 2,895$ patients had both AVF and AVG placements over the study period, statistical comparisons of the 2 patient groups were not performed.
* Unable to present data due to small number of patients.
ESRD, end-stage renal disease; AVF, arteriovenous fistula; AVG, arteriovenous graft.

Discussion

Our analyses shed light on the cost implications of specific access types, accounting for real-world changes in access type over time for patients, as opposed to cohorts of patients assigned to a single access category at baseline. Evaluating VA-related utilization and attributing resulting costs to specific types of VA placements are complex in the context of HD. VA-related event rates, including infections and interventions required to support matura-

Table 2. Per dialysis month healthcare resource utilization and costs for AVF or AVG placements[1] 2012–2014

	Access-related[2]			All-cause		
	AVF (*n* = 38,035)	AVG (*n* = 12,789)	significance[4]	AVF (*n* = 38,035)	AVG (*n* = 12,789)	significance[4]
Inpatient hospitalizations						
Percent of cohort with ≥1 admission, 2012–2014, % (*n*)	19.9 (7,582)	27.7 (3,541)	<0.001	73.7 (28,041)	78.8 (10,083)	<0.001
Number of admissions per dialysis-month, mean (SD)	0.03 (0.11)	0.06 (0.15)		0.26 (0.34)	0.35 (0.40)	
Number of admissions per dialysis-month, median (range)	0 (0–3)	0 (0–2)	<0.001	0.13 (0–5.6)	0.19 (0–3.0)	<0.001
Length of stay in days, mean (SD)	1.9 (5.5)	2.7 (6.2)		4.3 (5.5)	4.6 (5.7)	
Length of stay, median (range)	0 (0–259)	0 (0–159)	<0.001	3.5 (0–195)	4.0 (0–105)	<0.001
Cost per dialysis-month[3], USD, mean (SD)	662 (2,500)	1,186 (3,821)		3,027 (5,733)	3,811 (6,730)	
Cost[3] per dialysis-month, USD, median (range)	0 (0–58,575)	0 (0–123,491)	<0.001	868 (0–131,982)	1,167 (0–131,265)	<0.001
Outpatient visits						
Percent of cohort with ≥1 visit, 2012–2014, % (*n*)	88.1 (33,516)	85.3 (10,903)	<0.001	99.6 (37,879)	99.6 (12,733)	
Number of visits per dialysis-month, mean (SD)	0.35 (0.38)	0.40 (0.44)		11.1 (4.1)	10.2 (4.5)	
Number of visits per dialysis-month, median (range)	0.23 (0–6)	0.25 (0–6)	<0.001	12.5 (0–34)	12.0 (0–31)	
Cost per dialysis-month, USD, mean (SD)	662 (911)	932 (1,381)		3,139 (1,452)	3,034 (1,673)	
Cost per dialysis-month, USD, median (range)	351 (0–27,102)	436 (0–32,686)	<0.001	3,028 (0–55,211)	2,913 (0–23,305)	<0.001
Physician services						
Percent of cohort with ≥1 encounter, 2012–2014, % (*n*)	100 (38,035)	100 (12,789)	<0.001	100 (38,035)	100 (12,789)	<0.001
Number of encounters per dialysis-month, mean (SD)	0.73 (0.63)	0.98 (0.88)		5.5 (4.1)	5.9 (4.7)	
Number of encounters per dialysis-month, median (Range)	0.56 (0.03–16)	0.80 (0.03–13)	<0.001	4.3 (0.04–29)	4.5 (0.06–30)	0.006
Cost per dialysis-month, USD, mean (SD)	372 (439)	529 (679)		1,572 (1,580)	1,881 (1,801)	
Cost per dialysis-month, USD, median (range)	235 (0–9,934)	365 (0–20,828)	<0.001	1,057 (0–45,289)	1,209 (0–28,251)	<0.001
Other (skilled nursing facilities, home health, hospice)						
Percent of cohort with ≥1 service, 2012–2014, % (*n*)	1.1 (405)	2.2 (277)		82.9 (31,543)	87.6 (11,207)	
Cost per dialysis-month, USD, mean (SD)	3 (92)	9 (164)		770 (1,570)	879 (1,663)	
Cost per dialysis-month, median (range)	0 (0–14,562)	0 (0–10,672)	<0.001	84 (0–32,309)	117 (0–21,995)	<0.001
Total cost per dialysis-month, USD, mean	1,699	2,656		8,508	9,605	

[1] Accesses followed from placement to abandonment.
[2] Access-related utilization defined by ICD9 and HCPCS codes listed in online supplemental Table S1. Dialysis sessions are not considered access-related; all dialysis costs are reported in the all-cause outpatient category.
[3] Costs adjusted to 2017 USD.
[4] Nonparametric Wilcoxon tests were used to compare continuous variables between groups. Due to the large number of zeros for most measures, the variables were not lognormal distributed.
AVF, arteriovenous fistula; AVG, arteriovenous graft.

tion and patency, vary not just across types of VA but also over time. In addition, the type of VA a HD patient uses varies on a timeframe often shorter than typical observational study periods. We therefore examined the cost impacts of one access choice versus another using the arteriovenous access as the unit of cost analyses to build on prior studies in this area.

Adjusting for inflation, our all-cause cost estimates (Table 2) are comparable to those for all HD patients from the 2010 ADR (USD 2,473 per month for OP and USD 2,949 per month for IP utilization, 2017 USD) [6]. However, the ADR cost analysis created period prevalent patient cohorts defined by VA type in place during the last quarter of a calendar year, with costs for each cohort accumulated over the following year. By including prevalent patients based on an access in-place one quarter or more prior to the data collection period, costs related to the placement and the early initiation phase were excluded. We explicitly captured placement costs and the high-cost phase immediately after placement. Furthermore, the 2010 ADR method for identifying access-related events may greatly underestimate access-related costs since eligible claims from IP use, OP use, and physician/supplier utilization were required to be processed on the same day, a condition that occurs infrequently in actual administrative claim datasets. In contrast, we allowed up to a 5-day window for coincident access-related physician services and facility claims to be included.

Despite these differences with the methods of the 2010 ADR, the trends in cost results for AVGs versus AVFs are generally consistent with the ADR. The ADR found that access event costs were 150% higher for AVG versus AVF (USD 8,683 vs. 3,480, unadjusted) in 2008 [6, Fig. 18], while total expenditures by access type were 22.2% higher for AVGs versus AVFs (USD 73,081 vs. 59,792, unadjusted) for 2007, the most recent year reported [6, Fig. 19]. A study of 479 patients in a single medical center from 2006

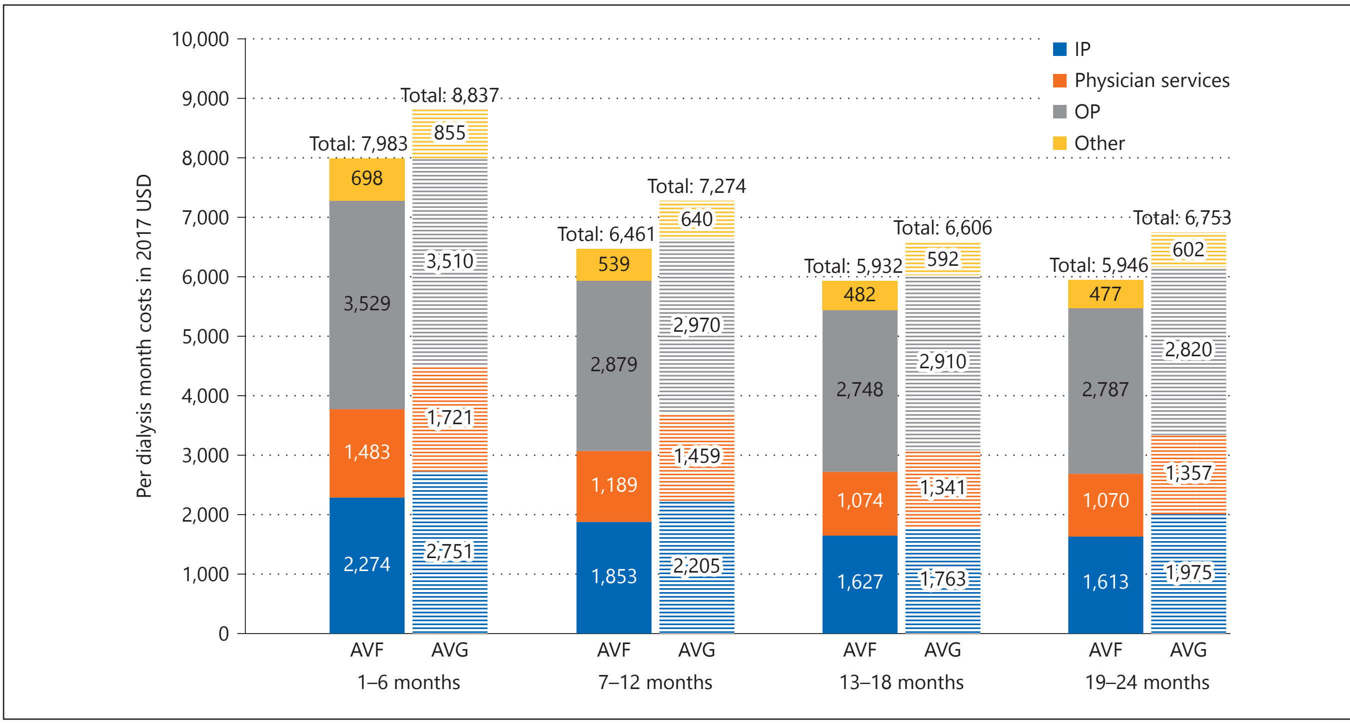

Fig. 1. All-cause costs per dialysis month for AVFs compared to AVGs, in 6-month increments. IP, inpatient; OP, outpatient; AVF, arteriovenous fistula; AVG, arteriovenous graft.

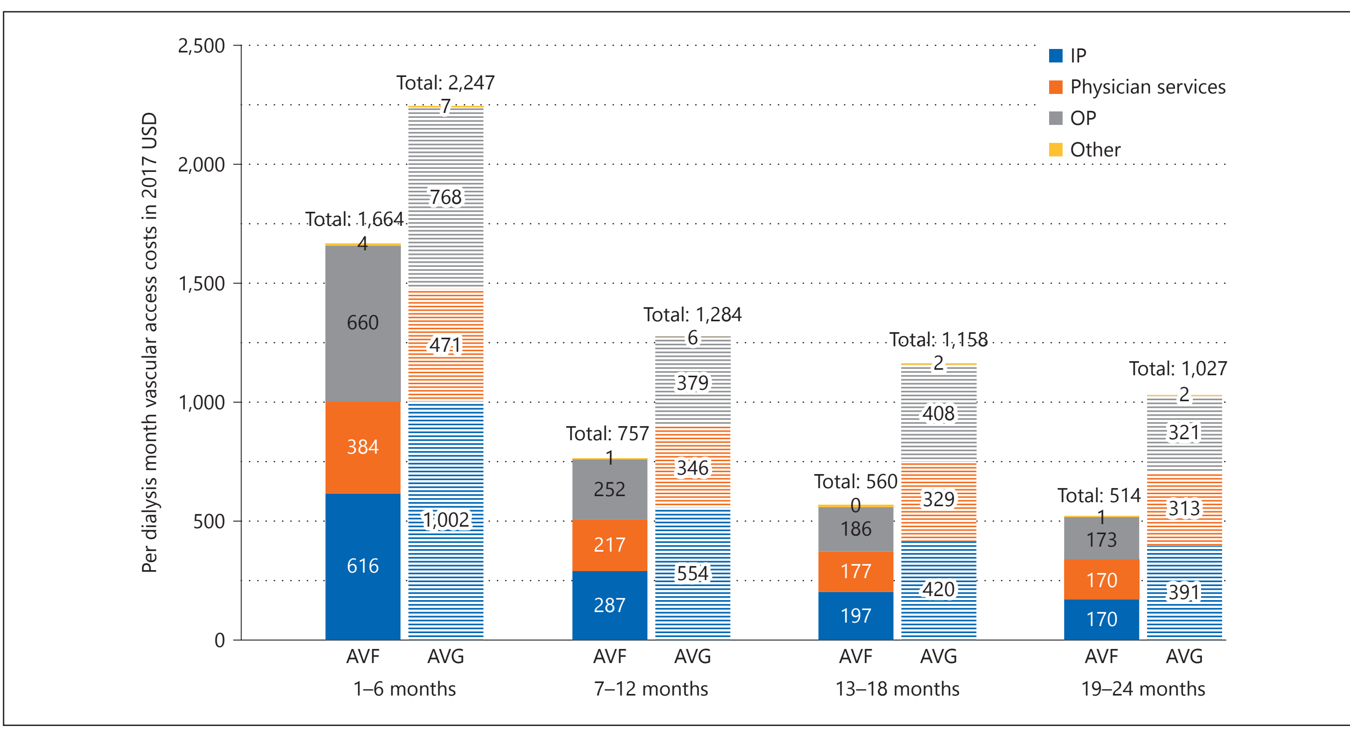

Fig. 2. Access-related costs per dialysis month for AVFs compared to AVGs, in 6-month increments. IP, inpatient; OP, outpatient; AVF, arteriovenous fistula; AVG, arteriovenous graft.

to 2012 did find higher costs for patients with AVFs than AVGs; however, AVF patients were 3 times more likely to transfer to OP dialysis and therefore lost to analysis. This change in the treatment setting would tend to bias remaining AVF patients to be less healthy and severely skew any comparison of results [7]. In our analysis, we did find that patients with an initial AVF placement were more likely to have multiple placements than patients with AVGs, which may lead to a downward bias in the mean costs attributed to AVFs. However, patients with AVFs had only 0.05 more subsequent placements than those with AVGs, which is unlikely to be a significant driver of VA-specific or total costs overall.

More recently, Thamer et al. [8] focused on costs of patients with AVF placements using USRDS over a 1-year period 2010–2011. While diagnoses and procedure codes similar to ours were used (online suppl. Text 1 and Tables S1, S5), the focus was on loss of patency and AVF nonuse, which complicate direct comparisons. However, weighting results based on the size of each cohort, the authors found monthly access-related costs to be USD 990 for patients initiating HD with a mature AVF to USD 3,090 for those initiating with a catheter and later receiving an AVF placement, which closely bound our access-related cost results for AVFs. Whether using placements or patients as the unit of analysis, we believe that approaches similar to Thamer et al. [8] and ours are the most appropriate method to evaluate VA-specific costs in HD.

Our results highlight 3 important aspects of VA costs in an incident HD population. First, this placement-level observational study demonstrated that VA-related costs place a significant burden on Medicare ESRD budgets, representing 20–28% of all-cause expenditures for these patients. This number is significantly higher as compared to VA costs for a period prevalent patient population, which was described as being between 6 and 12% in the 2010 USRDS ADR. However, our results are consistent with access-related costs described more recently by Thamer et al. [8] using similar albeit not identical methods. Our results also show that patient burden due to access-related utilization is substantial with about 15–20% of IP admissions and 36–43% of nondialysis session OP visits due to access events.

Second, access-specific costs for AVGs are significantly higher than those for AVFs, and this difference is very similar to the difference in overall costs of care for AVGs as compared to AVFs. Our results show higher access-specific resource use for AVGs in terms of IP admissions and lengths of stay, number of OP visits, and utilization of physician services. The lower per-unit cost and healthcare utilization of AVF may be influenced in part by our previously reported finding that 25% of AVF in this cohort were abandoned without use, in contrast to 14% of AVG [10].

Third, there is a significant downward trend in total and access-related costs in the months post-placement, with the greatest expenditures occurring soon after the start of HD. The first 6 months post-placement is very costly, and patients/placements who survive to the 1-year point experience far fewer access-related utilization. The factors driving these trends require further scrutiny and likely include interventions required to promote maturation, interventions to maintain patency, and infections.

Given the high access-related costs reflected in our results, what downstream programs and interventions should be considered to address these costs? Our findings should be a strong signal for all the stakeholders in this area to focus on decreasing VA costs in incident HD patients, particularly during the initial transition period from CKD to HD and in those patients who have had an AVG placed. In particular, our results emphasize an urgent and unmet need for improvements in process of care, innovation discovery, and payment programs to address this issue.

Suboptimal process of care may be a factor as well, particularly regarding AVF maturation in incident HD patients. Important process of care barriers that result in patients starting HD with only tunneled dialysis catheters include late or delayed referrals, competing demands on VA surgeons, variations in follow-up post-surgery, and limited training for cannulators. Each of these processes of care barriers, however, also represents an opportunity for local process of care innovation, which could potentially decrease VA-related costs. For example, in addition to specific interventions that target each of these process of care barriers, the introduction of a VA coordinator into the overall care plan could simultaneously target a number of these barriers.

Another approach to reduce VA care costs, particularly during the transition period for incident HD patients, is to develop novel therapies that enhance AVF maturation, decrease AVG stenosis, and reduce the high incidence of infection, thrombosis, and central venous stenosis associated with tunneled dialysis catheters. Such therapies are desperately needed, in view of the dismal 50% primary patency for both AVFs and AVGs. Some examples of such discovery innovation include sirolimus wraps and recombinant elastase for AVF maturation; tissue engineered biological vessels to reduce graft stenosis; and nitric oxide eluting catheters for the prevention of tunneled dialysis catheter complications.

An important barrier to both process of care and discovery innovation is reimbursement. In this context, the growing presence of global payment systems, such as the ESRD Seamless Care Organizations, could help to incentivize innovation, by better capturing potential improvements in clinical outcomes and resource utilization.

Our analysis has several limitations. The patients included in this study had Medicare primary coverage as of first ESRD service to ensure a complete medical history for each placement. Thus, included patients are somewhat older than the incident population overall as reported in the ADRs for our study period thereby limiting our conclusions to the population of older ESRD patients. CROWNWeb collects data for one HD session per patient-provider per month and data from the month's remaining HD sessions are not captured. Therefore, the data collection procedures may introduce some uncertainty into the assignment of costs to any given placement and in the assignment of temporary CVC use. However, these uncertainties apply equally to both AVFs and AVGs, and there is likely no differential bias introduced. Finally, while drugs covered under the bundle are captured in claims data, it is generally acknowledged that services not affecting payment may not be consistently captured in claims [12], and therefore the results presented may underrepresent true utilization. Despite these limitations, this analysis provides important insight into the significant utilization and costs associated with AVF and AVGs in a Medicare population.

This study indicates that costs due to VA are substantial and place a burden both on Medicare budgets and on patients. The results described in this manuscript represent the most detailed and thorough analysis of the healthcare costs associated with VA, in a very large number of incident HD patients. We hope that these results, in combination with a movement toward global payment systems, will facilitate a better process of care for VA and the use of innovative novel therapies to reduce both VA dysfunction and VA-related costs.

Acknowledgments

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Statement of Ethics

This study was exempt from Institutional Review Board review in accordance with 45 CFR 46.101(b; 4) as the data were previously collected and patients were deidentified before receipt of data.

Disclosures Statement

L.C.B., H.R., J.F., and R.J.N. were employees of EpidStat Institute at the time of this study, which received a grant from Humacyte. S.M.G., J.J.J., and T.L. are employees, consultants, and/or stockholders of Humacyte, Incorporated. S.M.G. is founder of and shareholder in InnAVasc Medical, Inc. P.R.-C. is a consultant or advisory board member for Humacyte, Cormedix, BD-Bard, WL Gore, Medtronic, Akebia, Bayer and Vifor-Relypsa. He is also the Founder and Chief Scientific Officer of Inovasc. The data reported here have been supplied by the USRDS. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.

Author Contributions

R.J.N., H.R., L.C.B., J.J.J., S.M.G., J.F., P.R.-C., and T.L. made substantial contributions to the conception or design of the study; were responsible for interpretation of data for the study; drafted and revised it critically for important intellectual content; gave final approval of the version to be published; and are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. H.R. was also responsible for the acquisition, analysis, and interpretation of data for the study.

References

1 Ravani P, Palmer SC, Oliver MJ, Quinn RR, MacRae JM, Tai DJ, et al. Associations between hemodialysis access type and clinical outcomes: a systematic review. J Am Soc Nephrol. 2013 Feb;24(3):465–73.

2 Xue JL, Dahl D, Ebben JP, Collins AJ. The association of initial hemodialysis access type with mortality outcomes in elderly Medicare ESRD patients. Am J Kidney Dis. 2003 Nov;42(5):1013–9.

3 Allon M, Dinwiddie L, Lacson E Jr, Latos DL, Lok CE, Steinman T, et al. Medicare reimbursement policies and hemodialysis vascular access outcomes: a need for change. J Am Soc Nephrol. 2011 Mar;22(3):426–30.

4 Lacson E Jr, Wang W, Lazarus JM, Hakim RM. Change in vascular access and mortality in maintenance hemodialysis patients. Am J Kidney Dis. 2009 Nov;54(5):912–21.

5 United States Renal Data System. 2018 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. Bethesda (Maryland): National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease; 2018.
6 United States Renal Data System. 2010 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. Bethesda (Maryland): National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease; 2010.
7 Al-Balas A, Lee T, Young CJ, Kepes JA, Barker-Finkel J, Allon M. The Clinical and Economic Effect of Vascular Access Selection in Patients Initiating Hemodialysis with a Catheter. J Am Soc Nephrol. 2017 Dec;28(12): 3679–87.
8 Thamer M, Lee TC, Wasse H, Glickman MH, Qian J, Gottlieb D, et al. Medicare Costs Associated With Arteriovenous Fistulas Among US Hemodialysis Patients. Am J Kidney Dis. 2018 Jul;72(1):10–8.
9 Woo K, Lok CE. New Insights into Dialysis Vascular Access: What Is the Optimal Vascular Access Type and Timing of Access Creation in CKD and Dialysis Patients? Clin J Am Soc Nephrol. 2016 Aug;11(8):1487–94.
10 Bylsma LC, Reichert H, Gage SM, Roy-Chaudhury P, Nordyke RJ, Fryzek J, et al. Clinical Outcomes of Arteriovenous Access in Incident Hemodialysis Patients with Medicare Coverage, 2012-2014. Am J Nephrol. 2019;49(2):156–64.
11 StataCorp LLC. Stata Statistical Software: Release 15. College Station, Texas, 2017.
12 Research Data Assistance Center. Strengths and Limitations of CMS Administrative Data in Research: Research Data Assistance Center; 2018. Available from: https://www.resdac.org/articles/strengths-and-limitations-cms-administrative-data-research.