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Clinical Outcomes of Arteriovenous Access in Incident Hemodialysis Patients with Medicare Coverage, 2012–2014

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Vascular access · Hemodialysis · Maturation · Arteriovenous fistula · Arteriovenous graft

Abstract
Background: Chronic hemodialysis requires a mode of vascular access through an arteriovenous fistula (AVF), a prosthetic arteriovenous graft (AVG), or a central venous catheter (CVC). AVF is recommended over AVG or CVC due to increased patency and decreased intervention rates for those that mature. AVG are preferred over CVC due to decreased infection and mortality risk. The aims of this study were to evaluate the lifespan of AVF and AVG in maturation, sustained access use, and abandonment. ***Methods:*** The United States Renal Data System (USRDS), Medicare claims, and CROWNWeb were used to identify access placements. Patients with a first end-stage renal disease (ESRD) service from January 1, 2012 to June 30, 2014 with continuous coverage with Medicare as primary payer and ≥1 AVF or AVG placed after ESRD onset were included. Maturation was defined as the first use of the access for hemodialysis recorded in CROWNWeb. Sustained access use was defined as 3 consecutive months of use without catheter placement or replacement. Accesses that were never used at any time post-placement were considered abandoned. ***Results:*** The cohort included 38,035 AVF placements and 12,789 AVG placements. Sixty-nine percent of AVF and 72% of AVG matured. Fifty-two percent of AVF and 51% of AVG achieved sustained access use. One quarter of AVF and 14% of AVG were abandoned without use as recorded in CROWNWeb. ***Conclusion:*** Although considered the gold standard for vascular access, only half of AVF and AVG placements achieved sustained access use. The USRDS database has inherent limitations but provides useful clinical insight into maturation, sustained use, and abandonment.

Introduction

An estimated 124,000 patients were diagnosed with end-stage renal disease (ESRD) in the United States in 2015; 87% began renal replacement therapy with chronic

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hemodialysis, 10% started peritoneal dialysis, and 3% received a kidney transplant [1]. Chronic hemodialysis requires reliable direct access to high volumes of blood such that adequate flow rates can be achieved for hemofiltration and waste removal. Furthermore, ideal vascular access modalities provide a long durable lifespan and low risk of complications [2]. The most common vascular access modalities include the arteriovenous fistula (AVF), prosthetic arteriovenous graft (AVG), and central venous catheter (CVC). The National Kidney Foundation recommends AVF as the optimal form of vascular access due to higher long-term patency rates and lower intervention rates than other access types, which can translate into benefits in both morbidity and mortality [2–4]. Clinical guidelines recommend the placement of AVF at least 6 months before the anticipated start of hemodialysis to allow for sufficient time for maturation and revision if necessary, and the placement of AVG 3–6 weeks before the start of hemodialysis [5]. Despite these guidelines, in 2015, 80% of US patients initiated dialysis with a catheter, only 17% with AVF, and only 3% with AVG, although at 1 year after initiation, 65% dialyzed using AVF and 15% with AVG [1].

Although AVF is currently recommended as the best vascular access method available, they are not without limitations. Rates of failure to mature have been reported between 20 and 50% [6]. Our recent systematic review and meta-analysis found that 21% of AVF were abandoned without use and only 26% were mature 6 months after placement [7]. The time from placement to use in hemodialysis is shorter among AVG than AVF, yet AVG may have higher rates of thromboses and infections over their lifespans [8]. While CVC is able to be used for dialysis immediately after placement, both AVF and AVG are preferred over CVC due to increased risks of infection, thrombosis, central vein occlusion, morbidity, and mortality with CVC. Further, the use of CVC is associated with poorer hemodialysis adequacy [2, 9, 10].

Patients in the United States who require permanent renal replacement therapy become eligible for Medicare health benefits, regardless of age, when kidney function has ceased and the patient has been on dialysis for at least 3 months [11]. Because statutory law requires Medicare to cover most individuals with ESRD in the United States, the associated administrative claims are an excellent source of healthcare utilization, costs, and outcomes information. The United States Renal Data Systems (USRDS) is a nationwide data collection system for kidney disease in the United States that began in 1988 [12] and incorporates Medicare data. In 2015, the USRDS made available the CROWNWeb clinical dataset, tracking patient-level, longitudinal data on clinical hemodialysis parameters, including detailed information on vascular access use. The first CROWNWeb dataset includes approximately 14 million clinical observations over the period from May 2012 to December 2014. This is the most recent dataset available, as there is a several-year lag in producing the dataset for research.

The aim of this study was to characterize the lifespan of AVF and AVG used for hemodialysis in the United States incident ESRD patients regarding access maturation, length of use, achievement of sustained access use, and abandonment.

Methods

Inclusion Criteria

The cohort included all US patients with a first ESRD service date between January 1, 2012 and June 30, 2014 that had continuous coverage with Medicare as primary payer from first ESRD service through the end of the study period, had one or more AVF or AVG placed after the onset of ESRD over the 2012–2014 period, and had CROWNWeb reports during the study period. We only included incident ESRD patients with Medicare primary coverage in order to have a complete history of vascular accesses for every patient and to track the access-related outcomes in both Medicare claims and CROWNWeb reports going forward. Included patients may have also had AVF or AVG placed before the onset of ESRD. However, only accesses placed after the onset of ESRD were included in the analyses, as accesses placed prior to ESRD onset may not be used for months or years, potentially introducing significant bias into the maturation analyses. The evaluation of CVC as a mode of vascular access was not included, as it is well established that CVC have no maturation time and a short lifespan, and long-term consistent use for hemodialysis is discouraged [2]. This study was determined to be exempted from Institutional Review Board review in accordance with 45 CFR 46.101(b; 4) as the data were previously collected and patients were de-identified before receipt of data.

Placements

AVF placements were identified from Medicare claims data using the Healthcare Common Procedure Coding System codes 36818 – 36821 and 36825. AVG placements were identified using code 36830. Accesses placed with codes 36825 and 36830 simultaneously were considered AVG. The clinical team (SG, PR-C, JL) evaluated the Healthcare Common Procedure Coding System code modifiers associated with some access placements to determine whether the modifier in fact represented a new access placement or simply described an aspect of another placement. Code modifiers evaluated by the clinical team are provided in online Supplemental Table 1 (for all online suppl. material, see www.karger.com/doi/10.1159/000495355).

Outcomes

Access maturation was defined as the first use of the access for hemodialysis in CROWNWeb. This is in conjunction with the maturation definition used by USRDS in their annual data reports (ADR) [1]. Because CROWNWeb only provides hemodialysis characteristics for one session monthly with sites reporting at any given day within the month, we set the date of maturation as the midpoint of the month. AVF were allowed up to 12 months after placement to mature and AVG were allowed up to 4 months after placement. AVF that did not mature within 12 months but had an intervention performed to assist maturation during the 9–12-month frame were allowed another 6 months post-intervention to mature. AVG that did not mature within 4 months but had an intervention to assist maturation during the 1–2-month time frame were allowed an additional 2-month post-intervention window to mature. Accesses that were used within 15 days of placement or outside of the allowed maturation times were classified separately as this was considered an implausible amount of time for an AVF or AVG to mature and likely represented a data error. Interventions to assist maturation were identified using the codes described in online Supplemental Table 2.

Sustained access use was defined as 3 months of AVF or AVG consecutive use for hemodialysis as recorded in CROWNWeb with no claims for catheter placement or replacement (online Suppl. Table 2). This outcome evaluated whether the access was able to be reliably used for hemodialysis after maturation without having to rely on a CVC. In the absence of a formal consensus or supporting literature to define an objective time frame of sustained use, we chose 3 months as a reasonable, relevant time frame based on clinical experience (JL, SG, PR-C). Because a vascular access may achieve sustained use and then become transiently dysfunctional, requiring intermittent use of a CVC during an intervention, we operationally defined whether an access ever achieved sustained use throughout its lifespan.

Accesses were considered abandoned without use under the following criteria: (1) the access was never used for dialysis as recorded in CROWNWeb before the end of the study period, (2) the access was never used for dialysis as recorded in CROWNWeb before a new AVF or AVG was placed, or (3) the access was never used for dialysis as recorded in CROWNWeb before the patient died within 2 years.

In addition to these outcomes, the total number of months spent dialyzing with a CVC after AVF or AVG placement was quantified, which included all non-consecutive months of CVC use throughout the access lifespan. The total number of months of AVF and AVG use for hemodialysis access, including non-consecutive months, was also quantified.

Follow-Up Period

Follow-up time was from the access placement date until the earliest date of patient death, transplant, kidney function recovery, loss to follow-up as recorded in CROWNWeb, hemodialysis discontinuation for another reason within 6 months of access placement, or December 31, 2014. As described in the inclusion criteria, accesses were not included if they were placed after June 30, 2014, as there was an insufficient follow-up time to observe outcomes, particularly maturation, given the dataset cutoff of December 31, 2014. Further, patients who had accesses placed within 6 months of the patient dying, receiving a transplant, recovering kidney function, being lost to follow-up (as recorded in CROWNWeb), or discontinuing hemodialysis for any other reason were deleted. These consisted of less than 1% of the accesses studied.

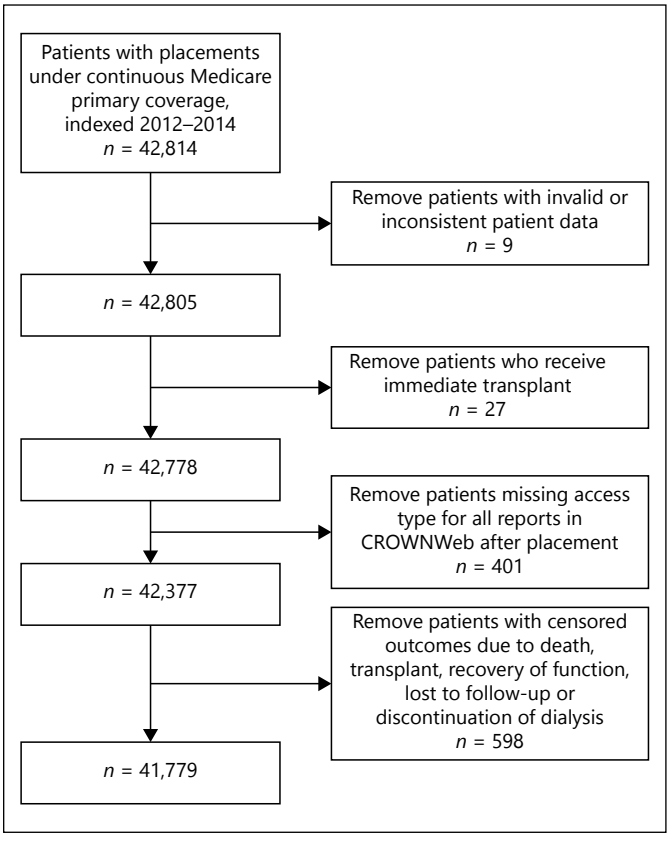

Fig. 1. Patient selection process.

Statistics

All statistical analyses were performed using Stata (version 15) [13]. Demographic and clinical characteristics of patients were presented using descriptive statistics. Maturation, abandonment, and sustained access use were calculated as proportions of all accesses.

Results

A description of the flow of patient selection is shown in Figure 1. Out of a total of 42,814 patients in USRDS with continuous Medicare primary coverage indexed from 2012 to 2014 that had AVF or AVG placements after onset of ESRD, 41,779 patients met our study criteria. AVF were placed in 33,091 patients and AVG in 11,583 patients (Table 1). The majority of the cohorts (71% of AVF and 75% of AVG) was 65 years of age or older at first ESRD service. Diabetes was the primary cause of ESRD in nearly half the cohorts followed by hypertension in 32% of AVF patients and 34% of AVG patients. Most patients had hypertension (88% in AVF and 89% in AVG) or diabetes (61% of AVF and 60% of AVG) as a comorbidity.

Table 1. Characteristics of ESRD patient cohort (indexed 2012–2014) with continuous Medicare coverage as primary payer and 1 or more AVF or prosthetic AVG placements at any time after the onset of ESRD (patient *n* = 41,779)

	AVFs	AVGs
Patients[a, b]	33,091	11,583
Placements	38,035	12,789
Number of placements per patient after onset of ESRD, median (range)	1 (1–7)	1 (1–6)
First access placement	28,663 (87)	10,494 (91)
Second access placement	3,974 (12)	986 (9)
Third access placement	404 (1)	93 (1)
Fourth access placement	40 (<1)	*
Fifth or greater access placement	10 (<1)	*
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	61 (0)	17 (0)
Missing	932 (3)	241 (2)
Year of first placement after ESRD onset, *n* (%)		
2012	10,890 (33)	3,918 (34)
2013	14,622 (44)	5,183 (45)
2014	7,579 (23)	2,482 (21)
Gender, *n* (%)		
Male	18,814 (57)	5,044 (44)
Female	14,277 (43)	6,539 (56)
Missing	0 (0)	0 (0)
Age at first ESRD service, *n* (%)	69.0 (12.2)	70.5 (12.2)
0–17	*	*
18–21	10 (<1)	*
22–44	1,402 (4)	434 (4)
45–64	7,882 (24)	2,440 (21)
65–74	12,051 (36)	3,979 (34)
75+	11,740 (35)	4,725 (41)
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)	*
Unknown	0 (0)	0 (0)
Hispanic ethnicity, *n* (%)		
No	29,101 (88)	10,391 (90)
Yes	3,970 (12)	1,185 (10)
Missing	20 (<1)	*
Alive at last follow-up date (December 31, 2014)	23,980 (72)	8,063 (70)
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)

Table 1. (continued)

	AVFs	AVGs
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)
Missing	25 (<1)	11 (<1)

[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] *n* = 2,895 patients had both AVF and AVG placements over the study period.

* Unable to present data due to small number of patients.

ESRD, end-stage renal disease; AVF, arteriovenous fistula; AVG, arteriovenous graft.

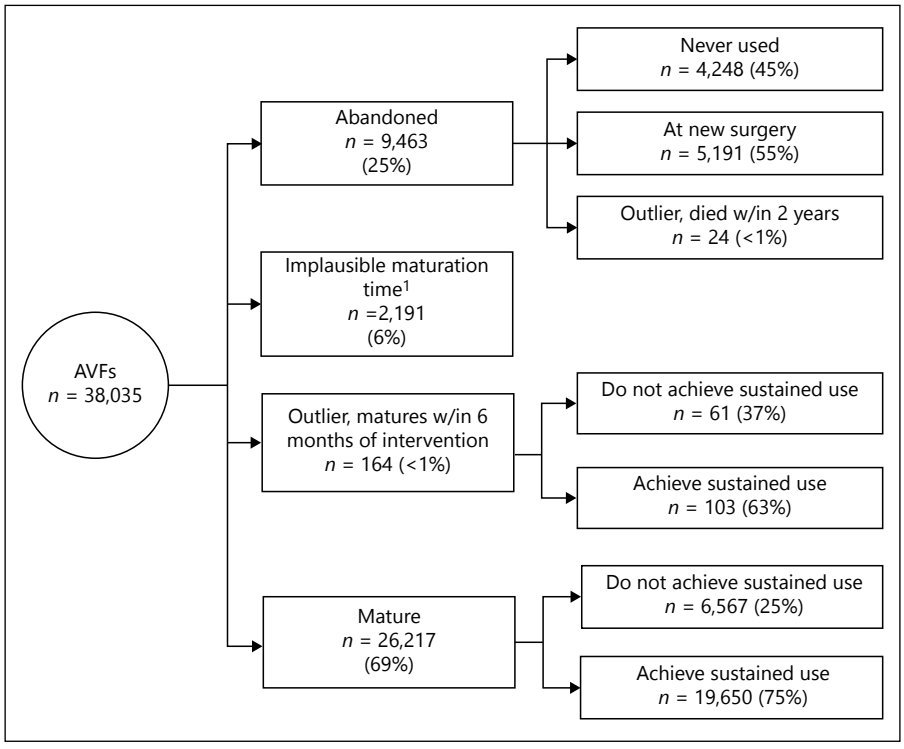

Fig. 2. Outcomes of arteriovenous fistula (AVF) placements.

Nearly all patients (93% of AVF and 90% of AVG) initiated dialysis with a catheter. There was a higher proportion of black patients (35 vs. 23%) and female patients (56 vs. 43%) in the AVG cohort than in the AVF cohort.

Figure 2 describes the lifespan of the 38,035 AVF placed in this cohort. Sixty-nine percent of the AVF matured either within 12 months of placement or within 6 months of an intervention. The median time to maturation was 114 days (range 15–542). The median total time of AVF use until the end of the study follow-up was 8 months (range 0–32) and the median time using a CVC for dialysis post AVF creation was 4 months (range 0–32). A quarter of AVF (25%) were abandoned without record of use, the most common cause of which was no record of use in CROWNWeb before placement of a new access (55% of abandoned AVF), followed by no record of use in CROWNWeb before the end of the study period (45% of abandoned AVF). Of the AVF that matured, 75% achieved sustained use, resulting in 52% of all AVF

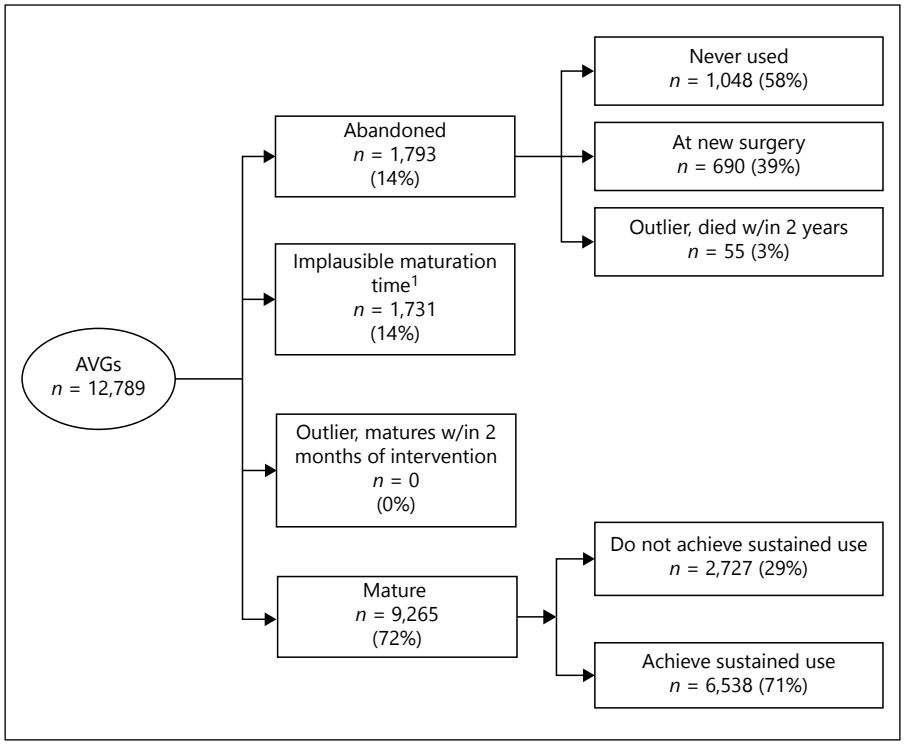

Fig. 3. Outcomes of prosthetic arteriovenous graft (AVG) placements.

achieving sustained access use. Approximately 6% of AVF (n = 2,191) had a recorded first use in CROWNWeb outside of the allotted maturation time frame (15–365 days without intervention or 6 months post intervention). Each outcome was also stratified by age groups to explore effect modification by age; however, no difference in outcome by age was observed (data not shown).

The lifespan of the 12,789 AVG placements is shown in Figure 3. Nearly three quarters (72%) of AVG matured, that is, had a first use for hemodialysis, within 4 months. The median time to maturation was 53 days (range 15–120). Seventy-one percent of mature AVG achieved sustained access use (51% of all AVG), and the median total time using an AVG was 7 months (range 0–32). The median time spent dialyzing using a CVC post AVG placement was 2 months (range 0–32). Fourteen percent of AVG were abandoned without use, the most common cause being no record of use in CROWNWeb before the end of the study period (58%) followed by no record of use in CROWNWeb before new access placement (39%). Fourteen percent of AVG (n = 1,731) had a recorded first use in CROWNWeb that was outside of the designed maturation window (15–120 days without intervention or 2 months post intervention). Outcome stratification by age group did not reveal any substantial differences in outcomes by age (data not shown).

Discussion

This cohort of incident US ESRD patients with an AVF and/or AVG placed for vascular access after ESRD onset demonstrated that although 69% of AVF were able to be used for hemodialysis, only 52% of all AVF were able to be used consistently for 3 months without reliance upon a catheter, as a measure of sustained access use. Similarly, 72% of AVG were able to be used at least once for hemodialysis, and 51% of AVG achieved sustained access use. These analyses establish that although many vascular accesses are able to be used for hemodialysis at least once, only about half of surgically created vascular accesses are able to be used consistently and considerable time spent dialyzing through a CVC may still be required. Notably, one quarter of AVF and 14% of AVG were abandoned without use as recorded in CROWNWeb. The causes of these relatively high rates of access abandonment merit further scrutiny. A complex set of process of care parameters and clinical complications have recently been shown to be associated with access maturation [14]. A similar set of process of care issues (pre-op management, e.g.,) and clinical events (thromboses, e.g.,) may also be found to be linked with access abandonment in prospective studies.

The definition of maturation has varied across published studies of vascular access. The National Kidney

Foundation Clinical Guidelines define fistula maturation as "a minimum of 6 mm in diameter with discernable margins when a tourniquet is in place, less than 6 mm deep, have a blood flow greater than 600 mL/min" [2]. Other definitions require that a fistula must be able to be routinely cannulated with 2 needles and deliver a minimum blood flow sufficient for the duration of dialysis [15]. While primary patency is often an academic clinical endpoint, the full access lifespan is typically measured as secondary patency, defined by the Society for Vascular Surgery as "the interval from the time of access placement until access abandonment, thrombosis, or the time of patency measurement including intervening manipulations (surgical or endovascular interventions) designed to reestablish functionality in thrombosed access." [16] Although an access may have matured and been used sufficiently for hemodialysis, a patient may dialyze via CVC temporarily if flow through the access becomes inadequate or the access becomes infected or requires a revision or intervention. A recent project from the Kidney Health Initiative, a partnership between the American Society of Nephrology and the US Food and Drug Administration, aimed to develop clinical trial end points for hemodialysis vascular access [17]. Although one of the end points included a period of reliable, consistent use of an access for hemodialysis [18], there is yet to be a definition of or consensus on an objective time period for clinically sustained use of an access.

Within this cohort, 31% of AVF placements failed to mature, which is similar to the ADR-reported rate of 35.9%. Additionally, the median time to maturation was 114 days, while the ADR reported a median time to maturation of 111 days [1]. A recent analysis of prevalent HD patients in USRDS with a new AVF observed a median time to maturation of 111 days with 36.2% of AVF having no evidence of use in CROWNWeb [19]. However, no post-placement outcomes other than maturation were evaluated and the study did not include AVG placements. We found that AVG also required a median length of 53 days between access placement and first use for hemodialysis, which was longer than the Dialysis Outcomes and Practice Patterns Study reported median time to first use of 29 days, although the present cohort may contain more elderly patients which may account for a longer maturation time [20]. In our dataset, time to first use may be slightly skewed due to CROWNWeb reporting only once per month on any given day. As such, we used the 15th of the month for maturation. Although the time to maturation was shorter among AVG than AVF, both access types had similar rates of maturation and sustained access use. We found that 25% of AVF were abandoned without use, which is comparable to the rate of 21% described in our previously reported meta-analysis [7]. Interestingly, the median time of access use was similar between both access types, with a median of 8 months for AVF and 7 months for AVG. Our follow-up period was not sufficient for a full analysis of patency, as the mean patency of AVF is around 28 months [7] and the median follow-up time in this cohort was 13 months (range 1–32).

Moreover, among the included patients, 6% of AVF and 14% of AVG had an implausible maturation time and were suggested to possibly represent data errors or incorrect coding by health care practitioners. From a clinical perspective, it is extremely uncommon for AVF to be usable by 4 weeks, and to an even lesser extent, 15 days. The safe use of AVF requires not only adequate dilation but thickening of the vein wall prior to cannulation to reduce the risk of bleeding, hematoma, and back wall injury. At a minimum, these attributes typically require at least 4–6 weeks to manifest sufficiently [2]. Since AVG do not require time for dilation, early cannulation is technically possible. However, it is common for AVG manufacturer instructions for use to recommend a waiting period of at least 2 weeks post implant prior to cannulation. In practice, it is common to allow 3–5 weeks for adequate wound healing, and most importantly, sufficient tissue incorporation into the graft prior to cannulation to reduce risk of bleeding and infection [2, 21]. Some AVG may have benefited from the placement of an "early access" graft, which could justify a time to first use of <15 days. However, "early access" grafts still comprise a small percentage of all prosthetic grafts placed 2012–2014, likely due to marginal performance and slow patient and provider adoption curves [22].

Patients initiating dialysis with a mature or maturing AVF or AVG may be clinically and demographically different from patients initiating dialysis with a catheter alone, which may impact placement-related outcomes such as maturation and abandonment [19, 23]. To evaluate whether patients with a mature or maturing AVF or AVG at first dialysis were different than patients initiating dialysis with a catheter alone, demographic and clinical characteristics were stratified by access at first dialysis (online Suppl. Table 3). Little difference was noted in demographic characteristics of patients with a mature or maturing AVF or AVG at first dialysis and those initiating dialysis with a catheter only.

The CROWNWeb dataset is the largest available database of hemodialysis patients' vascular access usage in

the United States. Our study was limited to the available CROWNWeb data from May 2012 to December 2014, and the corresponding patient Medicare claims for the same time period. For the majority of ESRD patients under age 65, Medicare coverage begins 90 days after the first ESRD service, rendering services and procedures (including access placements) covered by private insurance during the initial 90-day period undiscoverable. By restricting our cohort to those patients with established Medicare primary coverage as of first ESRD service, we were able to obtain complete medical history for each patient. As a result, the cohort studied is somewhat older than the incident population overall as reported in the ADR. A similar approach was undertaken in a recent analysis of USRDS data evaluating the costs of AVF among Medicare patients [24].

Additionally, CROWNWeb only reports hemodialysis characteristics for one hemodialysis session per patient per month. As most patients dialyze 3 times per week, data from the remaining hemodialysis sessions are not captured in this database. We acknowledge the limitations of using this "snapshot" of dialysis data to calculate rates of maturation, abandonment, and sustained use. Although the definition of maturation used in this study was not based on clinical parameters, it was used by the USRDS in their ADR and we feel was therefore justified in this USRDS analysis. Furthermore, the CROWNWeb database does not specify the rationale for placing an AVF or AVG, and residual confounding may be present due to patient-specific factors. These issues highlight the limitations of vascular access outcomes research using CROWNWeb. Despite these limitations, this analysis provides important insight into the patient experience of AVF and AVG and our proposed definition of sustained access use is a novel but practical operational measure of access efficacy that could be useful in observational studies or clinical trials of vascular access patients.

Conclusions

Within this cohort of ESRD patients with an AVF or AVG placed for hemodialysis access, 69% of AVF and 72% of AVG matured, that is, were able to be used for dialysis at least once. However, only about half of all created AVF and AVG achieved sustained access use, defined as 3 consecutive months of use for hemodialysis without claims for catheter placement or replacement. Twenty-five percent of AVF and 14% of AVG were abandoned without use. The USRDS CROWNWeb database, which is the largest and most complete source of vascular access data available in the United States, has inherent limitations but provides an interesting and useful source of clinical data to analysis access-related outcomes.

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This manuscript is not under consideration elsewhere.

Disclosure Statement

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Publication Disclaimer

Data reported here have been supplied by the USRDS. The interpretation and reporting of these data is the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the US government.

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