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Original Investigation

Hemodialysis Access Usage Patterns in the Incident Dialysis Year and Associated Catheter-Related Complications

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Background: Hemodialysis (HD) access is considered a critical and actionable determinant of morbidity, with a growing literature suggesting that initial HD access type is an important marker of long-term outcomes. Accordingly, we examined HD access during the incident dialysis period, focusing on infection risk and successful fistula creation during the first dialysis year.

Study Design: Longitudinal cohort.

Setting & Participants: All US adults admitted to Fresenius Medical Care North America facilities within 15 days of first maintenance dialysis session between January 1 and December 31, 2007.

Predictor: Vascular access type at HD therapy initiation.

Outcomes: Vascular access type at 90 days and at the end of the first year on HD therapy, bloodstream infection within the first year by access type, and catheter complication rate.

Results: Of 25,003 incident dialysis patients studied, 19,622 (78.5%) initiated dialysis with a catheter; 4,151 (16.6%), with a fistula; and 1,230 (4.9%), with a graft. At 90 days, 14,105 (69.7%) had a catheter, 4,432 (21.9%) had a fistula, and 1,705 (8.4%) had a graft. Functioning fistulas and grafts at dialysis therapy initiation had first-year failure rates of 10% and 15%, respectively. Grafts were seldom replaced by fistulas (3%), whereas 7,064 (47.6%) of all patients who initiated with a catheter alone still had only a catheter at 1 year. Overall, 3,327 (13.3%) patients had at least one positive blood culture during follow-up, with the risk being similar between the fistula and graft groups, but approximately 3-fold higher in patients with a catheter ($P<0.001$ for either comparison). Nearly 1 in 3 catheters (32.5%) will require tissue plasminogen activator use by a median of 41 days, with 59% requiring more than one tissue plasminogen activator administration.

Limitations: Potential underestimation of bacteremia because follow-up blood culture results did not include samples sent to local laboratories.

Conclusions: In a large and representative population of incident US dialysis patients, catheter use remains very high during the first year of HD care and is associated with high mechanical complication and bloodstream infection rates.

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INDEX WORDS: Hemodialysis access; arteriovenous fistula (AVF); arteriovenous graft (AVG); catheter; catheter infection; blood stream infection (BSI); catheter thrombosis; catheter complications.

Vascular access in hemodialysis (HD) patients generally is regarded as a critical and actionable determinant of morbidity and mortality. Studies have consistently shown that compared with arteriovenous grafts (AVGs), native arteriovenous fistulas (AVFs) are associated with enhanced survival, fewer occurrences of mechanical and infectious complications, longer patency, and reduced health care costs,[1-4] and that both are better than central venous catheters.[5,6] With the advances made by the Fistula First national movement, the rate of AVF use in prevalent HD patients has increased substantially, but 82% of US patients still initiate HD therapy by means of a catheter, and most of these (63.2% of all incident patients) have no concomitant arteriovenous access maturing when dialysis therapy is begun.[7] Even in patients followed up by nephrologists for 6 months or more, 75% initiate HD therapy with a catheter.

The high maturation failure rate for AVFs in particular prolongs the duration of catheter exposure,[8-10] which increases the risk of catheter-related infections and complications.[11,12] Our recent work,[13] along with other published data,[10,14,15] have suggested that initial HD access type is an important marker of long-term morbidity and mortality, which warrants a closer examination of its impact during the incident dialysis

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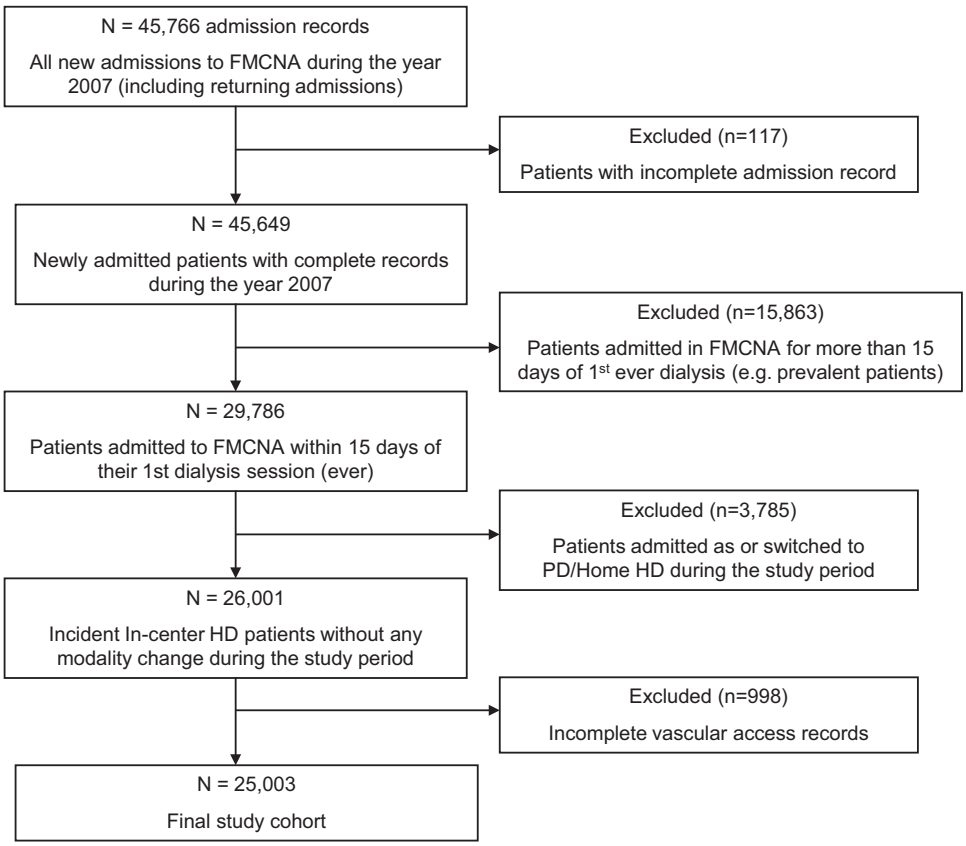

Figure 1. Cohort selection. Abbreviations: FMCNA, Fresenius Medical Care North America; HD, hemodialysis; PD, peritoneal dialysis.

period. Published studies examining vascular access during the incident dialysis period are hampered by small sample size[5,16] or cross-sectional design or are outdated. To add clarity to the contemporary literature in the era of the Fistula First initiative, we examined HD access type at the time of initiation, transitions in access type during the first year, and how these issues are associated with infectious and noninfectious catheter-related complications using data from a contemporary national cohort of incident HD patients.

METHODS

Arteriovenous access outcomes in the first year after dialysis initiation were analyzed for 25,003 incident HD patients who were admitted to Fresenius Medical Care North America (hereafter, "Fresenius") facilities between January 1 and December 31, 2007, and within 15 days of their first dialysis session after beginning maintenance HD therapy (Fig 1). The 15-day inclusion period was used to delineate a well-defined incident population with newly utilized vascular accesses, which minimized the chances of missing antecedent access events or complications. Most patients excluded by this criterion were new to Fresenius, but had previously undergone dialysis elsewhere.

Vascular access was recorded on admission and classified as AVF, AVG, or catheter. The presence of any HD catheter was classified as "catheter," even in instances when another maturing arteriovenous access was in place. Baseline demographic characteristics and comorbid medical conditions were recorded. Baseline values for albumin, hemoglobin, phosphorus, and equilibrated Kt/V were considered as the mean of observed values measured during the first 30 days after Fresenius admission for dialysis (Table 1).

Access status was updated for each patient when a new access was placed or used for first time or when a catheter was removed. Patients were followed up for 365 days or until censoring for death, kidney transplantation, withdrawal from dialysis, or recovery of kidney function. Reasons for censoring for all patients are listed in Table S1, provided as online supplementary material. Episodes of failure to mature and failure of previously functional arteriovenous accesses were abstracted from the electronic medical record. Blood culture results during the study period were obtained solely from a central laboratory (Spectra Laboratory), which processes ~85% of all blood cultures drawn in all Fresenius facilities; remaining samples are those sent to local laboratories on the weekend or for urgent results. Positive blood culture results, antibiotic use, and hospitalization for infections were equated with the likely presence of bloodstream infections (BSIs), absent collection of potentially corroborative clinical data in the database. Thrombotic access complications were abstracted from the database. The association between vascular access type and time to BSI was evaluated using Cox models. Unadjusted, case-mix–adjusted (adjusted for age, sex, race, and diabetes mellitus), and case-mix– and quality indicator–adjusted models (aforementioned plus baseline albumin, hemoglobin, phosphorus, and equilibrated Kt/V values) were estimated separately.

Because it was not possible to distinguish between catheter removal resulting from mechanical complication versus that resulting from maturation of a concomitant arteriovenous access, mechanical complications and recombinant tissue plasminogen activator (tPA) use were considered in the restricted cohort of patients who initiated dialysis therapy with a catheter and no other access. SAS 9.1 (SAS Institute) was used for all data analyses.

Table 1. Patient Demographics of Incident HD Patients

					Catheter Subgroups		
	All Patients	Fistula	Graft	Any Catheter	Catheter Only	Catheter + Fistula	Catheter + Graft
No. of patients	25,003 (100)	4,151 (16.6)	1,230 (4.9)	19,622 (78.5)	14,836 (59.3)	4,038 (16.2)	748 (3.0)
Age (y)	63.4 ± 15.3	63.6 ± 14.2	65.7 ± 13.8	63.3 ± 15.6	63.6 ± 15.8	61.9 ± 14.9	63.9 ± 14.5
Male sex	56.1	65.6	41.7	55.0	54.0	60.9	42.0
Race							
White	64.8	66.2	52.5	65.3	66.4	63.2	53.9
Black	30.0	28.2	41.3	29.7	29.1	29.7	41.6
Other	5.2	5.5	6.2	5.0	4.5	7.1	4.5
BMI (kg/m^2)	30.6	30.8	31.1	30.5	30.3	31.2	30.8
Diabetes mellitus	55.1	51.3	57.3	55.7	54.4	59.7	61.6
CAD	11.0	9.8	10.2	11.4	11.3	11.8	10.4
PVD	6.9	5.4	5.9	7.3	7.3	7.2	8.7
CHF	14.8	10.2	11.4	15.8	16.0	14.8	18.2
Laboratory values							
Albumin (g/dL)	3.5	3.7	3.6	3.4	3.4	3.5	3.3
Hemoglobin (g/dL)	10.7	10.8	10.8	10.7	10.7	10.7	10.5
Phosphorus (mg/dL)	4.7	4.8	4.6	4.7	4.7	4.8	4.6
eKt/V	1.3	1.3	1.4	1.3	1.3	1.3	1.4

Note: Values for categorical values given as number (percentage) or percentage; values for continuous variables given as mean or mean ± standard deviation. Patients are from a US nationwide sample admitted to Fresenius facilities between January 1 and December 31, 2007. Conversion factors for units: phosphorus in mg/dL to mmol/L, ×0.3229.

Abbreviations: BMI, body mass index; CAD, coronary artery disease; CHF, congestive heart failure; eKt/V, equilibrated Kt/V; HD, hemodialysis; PVD, peripheral vascular disease.

All patients consented for use of data for quality assessment and practice patterns at the time of HD enrollment, and institution review was waivered for quality improvement purposes. All Fresenius patients acknowledged receipt of Notice of Privacy Practices at HD enrollment, informing them of the use of clinical data for treatment, payment, and health care operations, among other appropriate uses and disclosures. These provider-initiated quality improvement studies are considered as being under the areas of treatment, payment, and health care operations and therefore do not require institutional review board approval or patient consent.

RESULTS

Patient Demographics

Mean age for the 25,003 HD patients studied was 63.4 ± 15.3 years, 56.1% were men, 64.8% were white, 30.0% were black, 5.2% were of other races, and 55.1% of patients had diabetes (Table 1). Overall, mean follow-up was 277 ± 130 (median, 365; interquartile range, 166-365) days. Most (78.5%) patients initiated dialysis with a catheter; 16.6%, with an AVF; and 4.9%, with an AVG. Catheter patients tended to be younger than AVF patients, and both were younger than AVG patients. Male patients had more AVFs and fewer AVGs relative to catheters. Patients with diabetes were disproportionately represented in the AVG group and under-represented in the AVF group. Black patients were more likely to have an AVG than an AVF, whereas white patients were more likely to have an AVF than an AVG. Catheter rate did not differ by race. In addition, congestive heart failure, coronary artery disease, and peripheral vascular disease were more prevalent in catheter patients, particularly compared with the AVF group.

Access Evolution Within the First Year of Dialysis

At dialysis therapy initiation, 4,151 (17%) patients had a functioning AVF, 1,230 (5%) had a functioning AVG, 14,836 (59%) had solely a catheter, 4,038 (16%) had a catheter and maturing AVF, and 748 (3%) had a catheter and maturing AVG. Of 20,242 patients alive at day 90, a total of 4,432 (21.9%) had an AVF (3,386 had a mature/maturing AVF on day 1), 1,705 (8.4%) had an AVG (1,012 had a mature/maturing AVG on day 1), and 14,105 (69.7%) had a catheter (13,704 had a catheter alone on day 1; Table S2).

As of 1 year on dialysis, death, or censoring for those who did not remain enrolled for 1 year, 90.5% of those who started with a functioning AVF continued with an AVF and 85.3% of those who started with a functioning AVG continued with an AVG (Fig 2). Of 14,836 (59%) patients who initiated HD with a catheter only, 3,526 (23.8%) were undergoing dialysis with an AVF at the end of 1 year, 1,499 (10.1%) had an AVG, 2,264 (15.3%) had both a catheter and a maturing AVF, 483 (3.3%) had a catheter and a

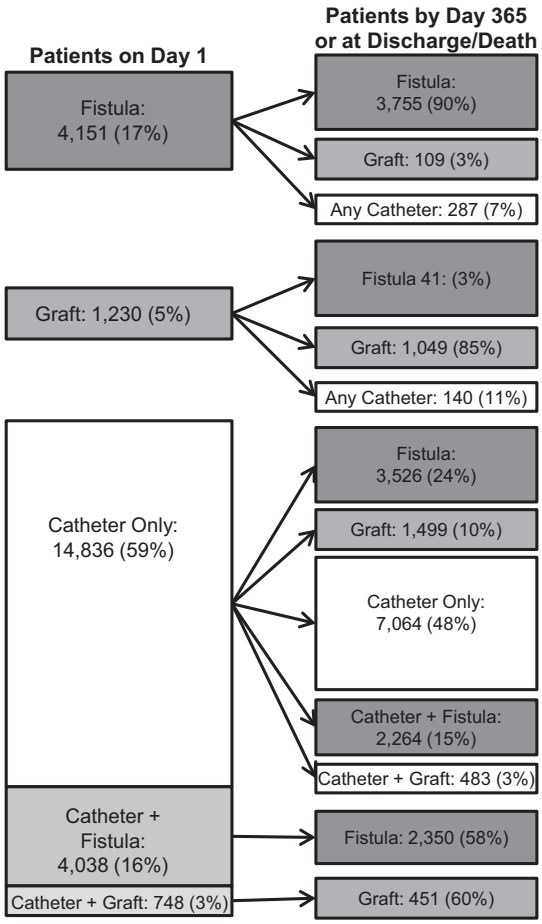

Figure 2. Evolution of hemodialysis (HD) access in the first year in 25,003 incident HD patients sampled from across the United States admitted to Fresenius facilities between January 1 and December 31, 2007.

maturing AVG, and 7,064 (47.6%) had a catheter only at the end of follow-up. Of 4,038 patients who started HD with a catheter and a concomitant AVF, 2,350 (58.2%) were dialyzing via AVF by the end of follow-up. Of 748 patients who initiated with a catheter and a concomitant AVG, 451 (60.3%) were undergoing dialysis with an AVG by the end of follow-up. In a total of 2,639,039 treatments administered during this 365-day period for all patients, 873,418 (33.1%) were delivered by AVF; 300,321 (11.4%), by AVG; and 1,465,300 (55.5%), by catheter.

BSIs Within the First Year

Overall, 3,327 (13.3%) patients had at least one positive blood culture result during follow-up. Kaplan-Meier curves for time to first BSI by access type are shown in Fig 3. Based on incident dialysis access type, catheter patients had a BSI event rate of 1.27/1,000 catheter-days, which was approximately 3-fold higher than that of patients receiving dialysis through an AVF or AVG ($P<0.001$ for catheter to AVF or catheter to AVG comparison; Table 2). Additionally, in the subset of 3,327 individuals who experienced a BSI during follow-up, median times to the first BSI were 85 days in patients with a catheter, 111 days in patients with an AVF, and 117 days in patients with an AVG. The case-mix and case-mix + quality indicator–adjusted hazard ratios for BSI demonstrated hazard ratios for catheters versus fistulas of 3.83 and 3.62, respectively (both $P<0.001$; Fig 4). Risk of BSI was not significantly different between individuals undergoing dialysis with fistulas versus grafts (Fig 4). Post hoc analysis of the actual access type at the time of BSI compared with baseline access type is shown in Table 3. The change in access type occurred in both directions, such that results were unchanged compared with the primary analysis.

Catheter Complications

Of 19,622 (78.5%) patients with catheters at dialysis therapy initiation, Kaplan-Meier event-free survival curves for each outcome and their composite are presented in Fig 5. First-ever use of tPA by 4,829 (32.5% of the total) patients occurred during fol-

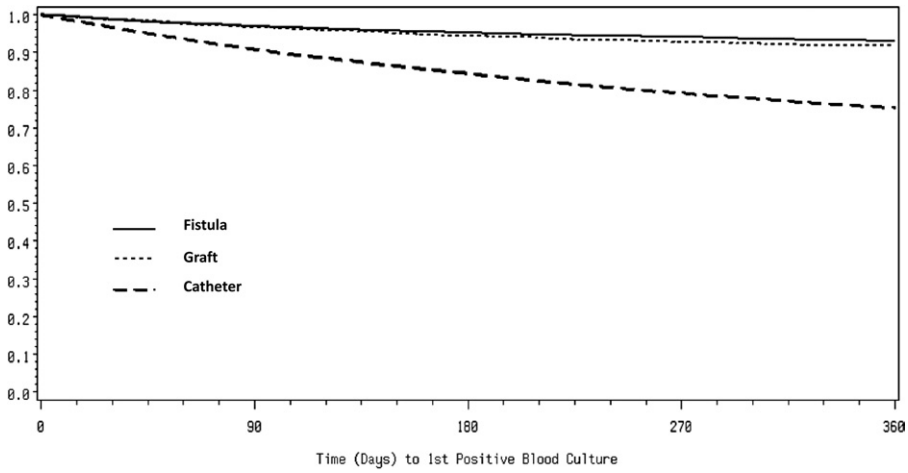

Figure 3. Kaplan-Meier curves for time to first positive blood culture in incident hemodialysis patients, by initiating access type for all patients (N = 25,003).

Table 2. BSI in the First Year on HD in Incident HD Patients

	All	Catheters	Fistulas	Grafts
Patients with BSI/total patients	3,327/25,003 (13.3%)	2,968/19,622 (15.1%)	267/4,151 (6.4%)	92/1,230 (7.5%)
Total no. of BSI episodes	5,441	4,798	490	153
Median time to first BSI (d)[a]	87	85	111	116.5
BSI rates/1,000-d	0.99	1.27	0.37[a]	0.39[b]

Note: Patients are from a US nationwide sample admitted to Fresenius facilities between January 1 and December 31, 2007.
Abbreviations: BSI, bloodstream infection; HD, hemodialysis.
[a]In patients with BSI-positive blood culture results.
[b]$P < 0.001$ compared with catheters.

low-up at a median of 41 days, and 2,860 (59.2%) of these had more than one tPA administration. Furthermore, 863 (17.9%) patients with catheters that had tPA instillation eventually had the catheter replaced for lack of usability (others may have had catheter removal as a result of infections or had the catheter removed with a new arteriovenous access in place). The 2,169 catheters present on dialysis initiation (14.6%) were replaced for the first time because of dysfunction (absent infection) at a median of 75 days. tPA use rate was 6.38/1,000 catheter-days, and catheter replacement rate was 1.05/1,000 catheter-days.

DISCUSSION

In the era since the introduction of the Fistula First initiative, we studied 25,003 incident HD patients for a nationwide contemporary look at vascular access course and evolution during the first year on dialysis therapy, with associated BSI and catheter complication rates.

Functioning fistulas and grafts at dialysis initiation had failure rates of 10% and 15%, respectively, at 1 year. Grafts were seldom changed to fistulas (3%). Forty-eight percent of all patients who initiate with a catheter alone still had only a catheter at 1 year. Fistulas that were maturing at the time of admission were used as the sole source of dialysis access only 42% of the time at 1 year, findings consistent with other reports.[8] These data add to the accumulating body of evidence showing that AVF and AVG maturation in dialysis patients frequently takes much longer than the conventional 3 months 2 weeks,[8-13] perhaps because of vessel health and surgical or cannulation techniques. Therefore, collaboration with surgical colleagues[7] and development of novel methods for identifying patients with chronic kidney disease at greatest risk of progression to end-stage renal disease, who are most likely to benefit from earlier permanent access referral, will be critical in increasing early permanent access use in incident HD patients. Although repeated attempts for permanent access can be made after the first year, patients are exposed to greater catheter use and attendant complications during the wait. Considered together with the high technical failure rate, additional studies focusing on permanent access referrals and access attempts in patients who are still undergoing dialysis through a central venous catheter at 1 year are necessary to identify reasons for continued catheter use, especially in those amenable to interventions.

As expected, most BSI events in the first year of dialysis were in patients with central venous catheters.

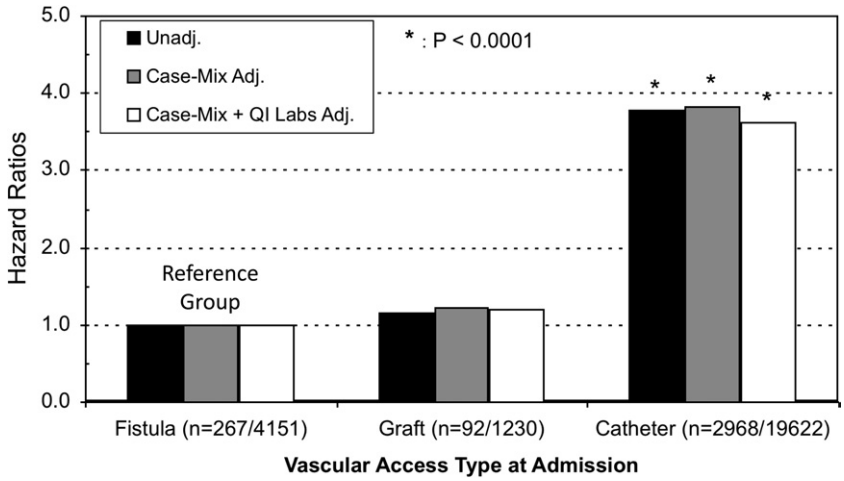

Figure 4. Cox model of risk of bloodstream infection by vascular access type. Case-mix Cox model pertains to the first year in incident dialysis patients and is adjusted for age, sex, race, diabetes status, body mass index, and comorbid conditions (diabetes, peripheral vascular disease, coronary artery disease, and congestive heart failure). Case-mix– and quality indicator (QI)- adjusted for the first 30 days includes laboratory results for albumin, hemoglobin, phosphorus, and equilibrated Kt/V. BSI, bloodstream infection.

Table 3. Misclassification of BSI Attribution

Baseline Access Type	Total	Access Type on Date of Positive Blood Culture Result		
		Catheters	Fistulas	Grafts
Catheters	2,968	2,928 (99.4)	25 (9.0)	15 (14.8)
Fistulas	267	12 (0.4)	254 (91.0)	1 (1.0)
Grafts	92	7 (0.2)	0 (0)	85 (84.2)
Total	3,327	2,947 (100)	279 (100)	101 (100)

Note: Misclassification using the intention-to-treat method (baseline vascular access type) compared with actual vascular access of record at the time of the blood draw for blood cultures with positive results. Values shown as number (percentage).

Abbreviation: BSI, bloodstream infection.

It is surprising that in patients with AVFs and AVGs in whom BSIs developed, the median time to event was only approximately 30 days longer than for catheter users. However, these data must be interpreted in light of there being many fewer BSIs in patients with AVFs and AVGs. Additionally, infections in fistulas or grafts are not often associated with bacteremia. Therefore, some of the observed BSI events in patients with AVFs and AVGs may have been unrelated to vascular access.

The main limitation of our study is the incomplete capture of BSIs. Approximately 15% of all culture specimens were sent to non–Fresenius laboratories. Although this may lead to a spuriously low event rate (and a spuriously high time-to-event value), the bias incurred is expected to be modest because ~85% of all events were likely to have been captured. Furthermore, because failure of data capture is unlikely to be related to access type, comparative analyses should be reasonably free of bias. To guard against misattribution resulting from access crossover, we performed post hoc analyses considering the actual access type in place at the time of BSI and observed no material change in results (Table 3). Another potential limitation is the uncertain validity of the source data related to vascular access. Although access data for these analyses were not formally validated, internal quality assurance testing done at Fresenius in other contexts indicates accuracy of about 90%-95%. Last, we acknowledge that there is limited precision regarding when conversion from catheter to arteriovenous access took place. Because the majority of morbidity seems to be related to the presence of an indwelling catheter, using the date of catheter extraction as a surrogate seems clinically grounded.

The observed data about tPA use and catheter replacements were obtained from patients who initiated dialysis therapy with only a catheter access, excluding patients who had a concomitant catheter with a maturing arteriovenous access. This conservative approach may have led to underestimation of the true utilization rate as a result of omission of mechanical complications of catheters in patients with concomitant maturing accesses. However, such an approach was necessary because the precise date of functional access transition is not reliably known in our data set; the period between established function of arteriovenous access and catheter removal is variable because only the date of catheter removal is reflected in the data during the study period. Nearly 1 in 3 (32.5%) catheters will require tPA use by a median of 41 days, with 59% requiring more than one tPA administration. The presence of biofilm and partially dissolved intra-/perilumen blood clots can function as a nidus for infection, potentially preventable by the development of a new antimicrobial catheter lock solution or more resistant catheters. Flow-related dysfunction requiring tPA and catheter replacement pose significant expense and burden on health care resource utilization while potentially contributing to the high infection risk in this group.[14,15,17-20] In addition, future studies should evaluate whether differ-

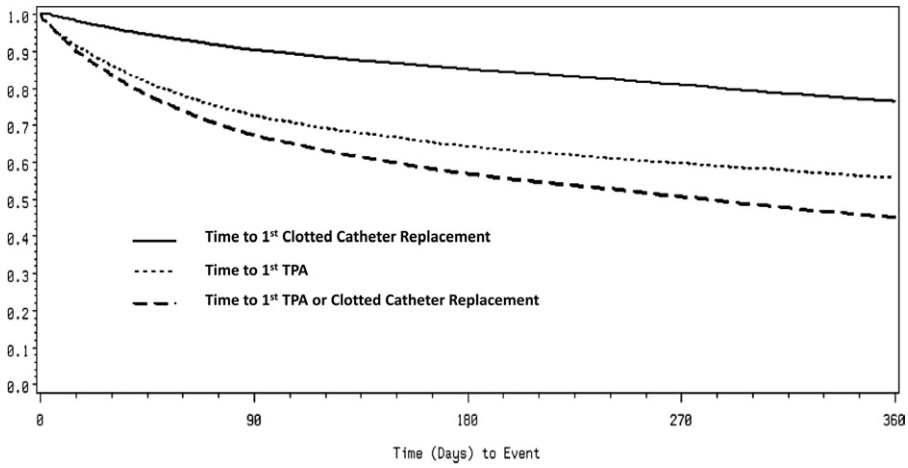

Figure 5. Kaplan-Meier curve on time to first episode of intervention in hemodialysis patients who initiated dialysis with solely a tunneled catheter, separated by interventions performed. Abbreviation: TPA, tissue plasminogen activator.

ences in handling of catheters by dialysis providers may decrease nosocomial contamination of catheters.

A growing body of evidence has suggested the importance of the type of vascular access used at HD initiation in terms of infectious complications, central vein stenosis,[21] and mortality risk.[16] Although the Fistula First initiative has significantly increased the total number of prevalent patients undergoing dialysis with an AVF,[22] our study illustrates that within the first year on dialysis therapy, catheter use remains the predominant access type, and transition to a permanent access often is delayed. This confirms prior reports in single-center experiences.[10] Although a fistula may not be the most appropriate type of dialysis access for select patients,[23] programs designed to increase functional arteriovenous accesses prior to the need for maintenance dialysis will be an important step in improving early morbidity and mortality during dialysis for most patients. In light of the significant risk posed by catheter use, arteriovenous access planning and preemptive access placement in patients with rapidly progressing moderate to severe chronic kidney disease should be a high priority.

Attendance in predialysis education programs for patients with chronic kidney disease has been shown to improve the rate of arteriovenous access use during dialysis initiation.[24-26] It has been recommended that this predialysis education should occur at or around a glomerular filtration rate of 30 mL/min/1.73 m^2, with access placement happening at a glomerular filtration rate of 20 mL/min/1.73 m^2, so that a mature access is reasonably predicted to be in place by the time glomerular filtration rate is decreased to 10 mL/min/1.73 m^2, also referred to as the "30-20-10 rule."[27,28] It also might be reasonable to consider selective placement of AVFs in patients who are undergoing peritoneal dialysis.[29] There are limitations for some patients with regard to lack of insurance coverage prior to dialysis therapy initiation that may require innovative solutions and advocacy for changes to Medicare policies.[30] More innovative programs that provide incentives to both nephrologists and surgeons while increasing accountability, such as the accountable care organizations proposed by the Department of Health and Human Services (composed of voluntary groups of physicians, hospitals, and other health care providers that agree to take responsibility for the care of a clearly delineated population of Medicare patients),[30,31] may also help.

In summary, in a large contemporary and representative population of patients who initiated HD in the United States, catheter use remained very high during the first year of HD care and was associated with high mechanical complication and BSI rates. These findings emphasize the need for multidisciplinary research and collaborative efforts to better identify patients at high risk of progression to end-stage renal disease, incentivize insurance coverage for prophylactic fistula placement, re-evaluate the role of AVGs to minimize catheter exposure, improve processes to drive efficient catheter conversion into arteriovenous accesses, and increase technological innovations for catheter care in patients who require dialysis through a central venous catheter. Collaboration from outside the renal community, including regulators, payers, surgeons, and hospitals, will be needed to effectively address the future of dialysis access care.

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Financial Disclosure: As of this writing, Ms Wang, Dr Lazarus, Dr Hakim, and Dr Lacson were or remain as employees of Fresenius Medical Care North America. Dr Brunelli has served as an advisor to Amgen, C.B. Fleet Company, and Proctor & Gamble. Dr Brunelli has received speaking honoraria from Fresenius Medical Care North America, and his spouse is employed by Astra Zeneca. Since completing this study, Dr Brunelli has become a full time employee of DaVita Clinical Research. Drs Xue and Ix declare that they have no relevant financial interests.

SUPPLEMENTARY MATERIAL

Table S1: Discharge breakdown of all study subjects at day 365.

Table S2: Access type at day 90.

Note: The supplementary material accompanying this article (http://dx.doi.org/10.1053/j.ajkd.2012.09.006) is available at www.ajkd.org.

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