

A Multicenter Randomized Clinical Trial of Hemodialysis Access Blood Flow Surveillance Compared to Standard of Care: The Hemodialysis Access Surveillance Evaluation (HASE) Study



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Introduction: Arteriovenous (AV) access thrombosis remains 1 of the most troubling AV access-related complications affecting hemodialysis patients. It necessitates an urgent and occasionally complicated thrombectomy procedure and increases the risk of AV access loss. AV access stenosis is found in the majority of thrombosed AV accesses. The routine use of AV access surveillance for the early detection and management of stenosis to reduce the thrombosis rate remains controversial.

Methods: We have conducted a multicenter, prospective, randomized clinical trial comparing the standard of care coupled with ultrasound dilution technique (UDT) flow measurement monthly surveillance with the standard of care alone.

Results: We prospectively randomized 436 patients with end-stage renal disease on hemodialysis with arteriovenous fistula (AVF) or arteriovenous graft (AVG) using cluster (shift) randomization to surveillance and control groups. There were no significant differences in the baseline demographic data between the 2 groups, except for ethnicity ($P = 0.017$). Patients were followed on average for 15.2 months. There were significantly less per-patient thrombotic events (Poisson rate) in the surveillance group (0.12/patient) compared with the control group (0.23/patient) ($P = 0.012$). There was no statistically significant difference in the total number of procedures between the 2 groups, irrespective of whether thrombectomy procedures were included or excluded, and no statistically significant differences in the rate of or time to the first thrombotic event or the number of catheters placed due to thrombosis.

Conclusion: The use of UDT flow measurement monthly AV access surveillance in this multicenter randomized controlled trial reduced the per-patient thrombotic events without significantly increasing the total number of angiographic procedures. Even though there is a trend, surveillance did not reduce the first thrombotic event rate.

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KEYWORDS: arteriovenous access blood flow; arteriovenous access thrombosis; arteriovenous fistula; arteriovenous graft; hemodialysis access surveillance; ultrasound dilution technique

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The role of AV access monitoring in end-stage renal disease patients supported with hemodialysis is well established and is not controversial.^{1–5}

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Contrarily, the routine use of hemodialysis AV access surveillance for the purpose of reducing access-related complications such as access thrombosis or prolonging hemodialysis access life is still debatable due to the conflicting results of published studies.^{6,7} Hemodialysis access thrombosis is a worrisome complication because it requires an urgent thrombectomy procedure to maintain the hemodialysis patient's lifeline (i.e., dialysis access) in order to provide a potentially lifesaving hemodialysis

treatment.^{8–10} Additionally, access thrombosis is associated with shorter AV access life and is the leading cause of AV access loss.⁹ The clinical practice guidelines and clinical practice recommendations (National Kidney Foundation Kidney Disease Outcomes Quality Initiative) 2006 updates¹¹ defines surveillance as “the periodic evaluation of the vascular access by using a test that may involve special instrumentation and for which an abnormal test result suggests the presence of dysfunction.” Surveillance using hemodialysis access blood flow is 1 of several recognized surveillance methods and is preferred by many experts to detect common stenotic lesions of AV accesses that precede thrombotic events.^{5,7} Despite the 2006 Kidney Disease Outcomes Quality Initiative guidelines categorizing surveillance with blood flow as the preferred method for AVF and AVG, its routine use is low and continues to be controversial.⁶ Additionally, the 2019 Kidney Disease Outcomes Quality Initiative guidelines¹² indicated that there is inadequate evidence to recommend using routine AVF surveillance in addition to routine standard clinical monitoring to improve AVF access patency. The Kidney Disease Outcomes Quality Initiative also did not suggest routine AVG surveillance in addition to routine clinical monitoring to improve AVG access patency.¹²

The main purpose of monthly blood flow surveillance is the early detection of hemodialysis AV access circuit stenotic lesions and preemptive treatment with percutaneous transluminal angioplasty of the lesion before it leads to clinical outcomes such as low dialysis adequacy, high recirculation, AV access thrombosis, and many others. It is believed that the presence of vascular stenosis completes the Virchow’s triad of endothelial injury, stasis, and hypercoagulability leading to hemodialysis AV access thrombosis.⁸ Therefore, because vascular stenosis is the most common reason leading to AV access dysfunction and is found in most thrombosed AV accesses,^{9,10,13,14} we examined the utility of AV access blood flow surveillance for the early detection of stenotic lesions and the effect of preemptive percutaneous transluminal angioplasty on AV access thrombosis. Our primary hypothesis was that blood flow surveillance would decrease the rate of access thrombosis. The secondary hypotheses were that surveillance would increase the time to the first thrombosis event, increase the number of angioplasty procedures, decrease the number of thrombectomy procedures, and decrease the rate of tunneled hemodialysis catheter placement.

METHODS

Population Inclusion and Exclusion Criteria

The inclusion criteria comprised patients with end-stage renal disease receiving hemodialysis via upper extremity AV access (AVF or AVG) and between the ages of 18 and 80. The exclusion criteria included patients less than 18 years of age or greater than 80 years of age, patients requiring surgical intervention on the AV access, patients with a history of access thrombosis (1 or more access thrombosis of the current AV access), patients with signs of access infection, patients with an active malignancy, patients with a life expectancy of less than 6 months, and/or patients unable to consent for the study. The study was approved by corresponding institutional review boards for each participating site, and written informed consent was obtained from each patient before enrollment.

Clinical Trial Design and Treatments

The Hemodialysis Access Surveillance Evaluation (HASE) study is a prospective, randomized, multicenter clinical trial conducted between 2014 and 2019. Patients were randomized using cluster (i.e., dialysis shift) randomization to receive either monthly surveillance by UDT flow measurement using the Transonic HD03 Hemodialysis Flow Monitor (Transonic Systems Inc., Ithaca, NY) in addition to the standard of care (surveillance group) or the standard of care alone (control group). Both groups were followed for the duration of the study for 2 years at the sites in each national location. The enrollment period was 6 months at each site. The standard of care protocol includes performing at least 1 monthly physical examination of the AV access by a trained care provider for the duration of the study in addition to completing a monthly questionnaire for the purpose of detecting the following clinical indicators: the development of prolonged bleeding for longer than 30 minutes, upper extremity edema (ipsilateral to AV access or bilateral), difficulty with AV access cannulation, aspiration of clots during cannulation, aneurysmal formation that met the criteria for referral,¹¹ access pressures that prevent normal hemodialysis machine operation (high venous pressure > 250 mm Hg on 3 or more consecutive dialysis treatments, negative arterial pressure < –250 mm Hg on 3 or more consecutive dialysis treatments), lower than target monthly Kt/tv that cannot be explained by other factors, and a high recirculation rate of more than 10%. Recorded high recirculation rates by the urea method were rechecked again using the Transonic HD03 Hemodialysis Flow Monitor for confirmation.

Principal investigators and biostatisticians were blinded to group assignment. Nurses and dialysis personnel were provided the monthly UDT flow measurements of patients randomized to the surveillance group, which were used according to their standard of practice. In order to avoid crossover of patients, if a patient needed to switch his or her dialysis schedule, we attempted to switch the patient to the shift that matched his or her initial assigned group. Otherwise, the patient switched groups. Sixteen patients switched groups; 14 switched from the surveillance group to the control group, 1 of whom switched back, and 2 switched from the control group to the surveillance group. In 18 patients, only 1 visit was recorded, and 4 patients had missing first visit demographic data. Patients were censored from the study after a surgical revision, which occurred in 3 control patients at 5, 9, and 14 months and in 2 surveillance patients at 2 and 18 months. Ninety of 207 control patients completed all 24 visits, and 58 of 229 surveillance patients completed 24 visits.

UDT

Blood flow measurement was performed by UDT using the Transonic HD03 Hemodialysis Flow Monitor on the study group on a monthly basis. Measurement was performed during the first 90 minutes of the hemodialysis treatment to eliminate error caused by a decrease in cardiac output or blood pressure related to ultrafiltration or hypotension. Patients with blood flow less than 600 ml/min in AVGs or less than 500 ml/min in AVFs and patients with blood flow above 1000 ml/min in whom AV access blood flow declined by more than 25% over 4 months were referred for further evaluation with AV access angiogram. UDT is used as a complementary tool to standard practice.

Statistical Methods

In intention-to-treat analysis, our primary goal was to examine whether the additional use of transonic UDT monthly surveillance reduced the rate of AV access thrombosis. For the primary outcome, we compared the 2 groups for the rate of access thrombosis where the null hypothesis was that the rate of access thrombosis was not different. The secondary outcomes were analyzed using a step-down sequential testing procedure in the following prespecified hierarchy to control for overall type 1 error. The secondary outcome null hypotheses tested were as follows: (i) patients screened monthly with UDT will not have a time to thrombosis that is different than control patients, (ii) patients screened monthly with UDT will not have a number of angioplasty procedures that is different than control patients, (iii) patients screened monthly with UDT will not have a number of thrombectomy procedures that is different than control patients, and (iv)

Table 1. Baseline demographic and clinical data of the study groups

Variable	Control group	Surveillance group	P value
Number (total 436)	207	229	
Age (years)	61.826 ± 11.942	60.996 ± 11.855	0.467
Age of current access (years)	4.692 ± 4.401	4.781 ± 4.145	0.833
Location of access: upper arm	141/205 (69)	176/229 (77)	0.058
Side of body access: left	158/205 (77)	176/229 (77)	0.957
Type of access			0.649
AVF	173/204 (85)	196/227 (86)	
AVG	31/204 (15)	31/227 (14)	
Previous access	48/202 (24)	55/228 (24)	0.93
Previous catheter	145/203 (71)	177/227 (78)	0.118
Female	76/156 (49)	80/156 (51)	0.671
Ethnicity			0.017
Black	43/205 (21)	43/229 (19)	
Hispanic	93/205 (45)	136/229 (59%)	
White	61/205 (30)	40/229 (18)	
Asian/Pacific Islander	5/205 (2)	8/229(4)	
Diabetes mellitus	130/204 (64)	144/229 (63)	0.856
PVD	28/205 (14)	31/226 (14)	0.986
CAD	49/205 (24)	59/229 (26)	0.654
HTN	168/205 (82)	200/227 (88)	0.072
Buttonhole site	4/204 (2)	4/228 (2)	0.874
Geographic location of patients			
New York	60/207 (29)	33/229 (14)	
Florida	84/207 (41)	112/229 (49)	
California	63/207 (30)	84/229 (37)	

AVF, arteriovenous fistula; AVG, arteriovenous graft; CAD, coronary artery disease; HTN, hypertension; PVD, peripheral vascular disease.
Data presented as mean ± standard deviation or n/N (%).

patients screened monthly with UDT will not have a rate of tunneled hemodialysis catheter that is different than control patients. Before study initiation, the sample size was estimated using a power analysis based on the χ^2 test for proportions assuming that during 2 years the proportion of patients with thrombosis in the control group would be 34% and in the surveillance group 24% with $\alpha = 0.05$, $\beta = 0.80$, and 2-sided (testing benefit and harm). The sample size was calculated before and after accounting for loss to follow-up or transplant of 5% per year and mortality of 10% per year, and there were 342 and 443 patients per group, respectively. The study was terminated before achieving these goals because of lower than expected recruitment and a lack of resources.

Because events were relatively infrequent, per-patient and per-visit rates of thrombosis and secondary outcomes were assessed using a 2-sample Poisson rate test (Minitab statistical software, Minitab, LLC, State College, PA). An estimated difference in the rates is reported together with the respective 95% confidence interval (CI) for the difference. In addition, the time to the first occurrence of thrombosis and the first occurrence of catheter placement due to thrombectomy were assessed by Kaplan-Meier plots, and *P* values were estimated by log-rank tests. No multiplicity correction was applied for the exploratory secondary hypotheses.

Table 2. Hemodialysis Access Surveillance Evaluation study primary and secondary outcome results

Variable	Control group	Surveillance group	Difference (95% confidence interval)	P value
Number of patients	207	229		
Total thrombotic events	47	28		
Number of patients with 1 or more thrombotic events	37	27	0.073 (χ^2)	
Number of patients with no thrombotic events	170	202		
Thrombotic events per patient ^a	0.227	0.122	-0.104 (-0.184 to -0.026)	0.012 ^a
Total number of visits	3353	3278		
Thrombotic events per visit	0.014	0.0085	-0.005 (-0.011 to -0.0001)	0.037 ^b
Total number of procedures (including thrombectomies)	203	227		
Number of patients with 1 or more procedures	117	125	0.685 (χ^2)	
Number of patients with no procedures	90	104		
Procedures per patient ^a	0.981	0.991	0.011 (-0.176 to 0.197)	0.95 ^c
Number of angiograms with or without angioplasty (excluding thrombectomies)	148	191		
Number of patients with 1 or more procedures	92	106	0.699 (χ^2)	
Number of patients with no procedures	115	123		
Procedures per patient ^a	0.715	0.834	0.119 (-0.046 to 0.284)	0.18 ^d

^aP value from 2-sample Poisson rate difference.

^bChi-squared or Fisher's exact test.

^cPoisson rate.

RESULTS

Patient Characteristics

A total of 436 patients were randomized using cluster (i.e., dialysis shift) randomization to the surveillance group ($n = 229$) or control group ($n = 207$). Table 1 shows the demographic and clinical data for the study groups. There were no statistically significant differences between the 2 groups, except for ethnicity ($P = 0.017$). Patients were enrolled from 3 national locations (Albany Medical Center, Albany, NY [93/436 total, 21%]; University of Miami Miller School of Medicine, Miami, FL [196/436, 45%]; and California Kidney Specialists, San Dimas, CA [147/436, 34%]). Eighty-six percent of patients in the surveillance group had an AVF compared with 85% of patients in the control group. Most patients had an upper arm-based AV access (77% and 69% in the surveillance and control groups, respectively).

Outcome

There was a total of 3278 visits for the surveillance group and 3353 visits for the control group during the study. During the study follow-up period, 27 thrombotic events occurred in the surveillance group, and 37 thrombotic events occurred in the control group. There was a statistically significant difference in thrombotic events per patient (0.122 vs. 0.227; difference -0.104 ; 95% CI: -0.026 to -0.184 ; $P = 0.012$) in the surveillance group compared with the control group, respectively. Similarly, there was a statistically significant difference between the groups in thrombotic events per visit (0.0085 vs. 0.014; difference -0.005 ; 95% CI: -0.0001 to -0.011 ; $P = 0.037$).

The secondary outcomes are depicted in Table 2. There was no statistically significant difference in the

rates of angiographic procedures per patient when thrombectomy procedures were included (0.991 vs. 0.981; difference 0.011; 95% CI: -0.176 to 0.197 ; $P = 0.95$) or when thrombectomy procedures were excluded (0.834 vs. 0.715; difference 0.119; 95% CI: -0.046 to 0.284 ; $P = 0.18$) between the surveillance group and the control group, respectively. Similarly, there was no statistically significant difference in the number of catheters placed due to AV access thrombosis (0.039 vs. 0.053 catheters per patient; difference -0.014 ; 95% CI: -0.054 to 0.027 ; $P = 0.65$) between the surveillance group and the control group, respectively. There were no statistically significant differences between the 2 groups in the proportion of patients to time to first thrombectomy (thrombectomy-free survival; $P = 0.149$; Figure 1), first catheter placement due to thrombosis (catheter-free survival; $P = 0.62$; Figure 2), or first angiogram not associated with thrombosis ($P = 0.36$; Figure 3). Table 3 shows subgroup analyses and interactions. No adverse events were reported due to the monthly UDT blood flow surveillance measurements or standard of care measures.

DISCUSSION

This HASE study demonstrates that the use of monthly surveillance using UDT flow measurement coupled with the standard of care reduced per-patient and per-visit thrombotic event rates compared with the standard of care alone. This benefit was not associated with an increased number of procedures per patient regardless of whether thrombectomy procedures are included or excluded from the analysis. Monthly UDT flow measurement can be used as complementary to the standard of care in clinical practice.

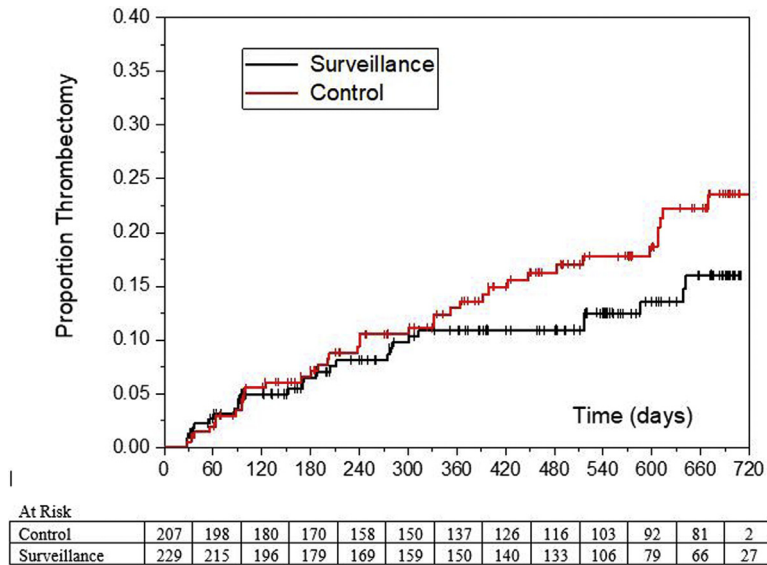


Figure 1. Thrombectomy-free survival analysis for the surveillance group (black) and the control group (red). $P = 0.149$ by the log-rank test. The number at risk for time interval is shown in the table. Censoring is indicated by the vertical symbols; note the vertical axis break.

Several observational studies have shown conflicting results of the benefits of a surveillance program in reducing access thrombosis, hospitalization, and cost burden.^{5,10,13,15–31} However, small study sample sizes limited the validity and value of the results.^{5,22,32} National debates continue regarding the value and cost-effectiveness of a surveillance program.^{6,7} Ravani *et al.*²⁵ conducted a systematic review and meta-analysis of randomized trials. This included 14 trials with a total of 1390 participants. They concluded that preemptive angioplasty of AV access stenosis did not prolong AV access longevity

but had a significant effect on risk for thrombosis. Muchayi *et al.*²² performed a meta-analysis of randomized clinical trials assessing hemodialysis access thrombosis based on access flow monitoring only. They included 7 studies (with 727 accesses, 395 AVFs and 332 AVGs) that met the required information for the analysis. They concluded that the benefit of AV access surveillance using access blood flow to lower the risk of thrombosis was uncertain with only a marginal benefit in the subgroup of patients with AVF. In the absence of a well-designed and powered multicenter randomized, controlled

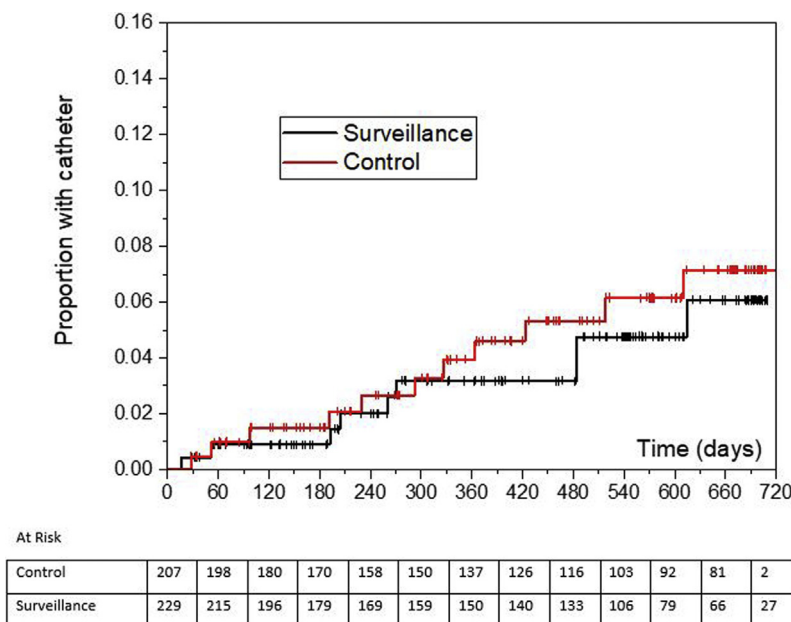


Figure 2. Catheter due to thrombosis-free survival analysis for the surveillance group (black) and the control group (red). $P = 0.62$ by the log-rank test. The number at risk for time interval is shown in the table. Censoring is indicated by the vertical symbols; note the vertical axis break.

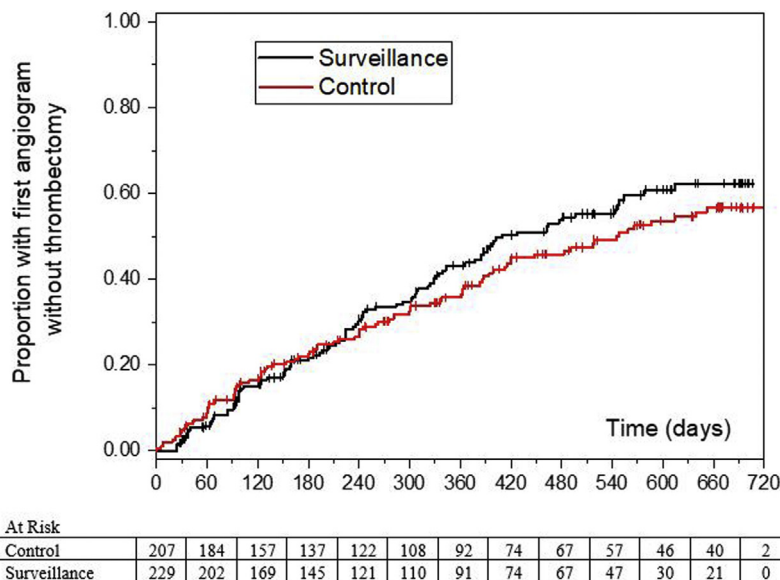


Figure 3. The proportion of patients free of an angiogram not associated with thrombosis for the surveillance group (black) and the control group (red). $P = 0.36$ by the log-rank test. The number at risk for time interval is shown in the table. Censoring is indicated by the vertical symbols.

trial, drawing a conclusion from these meta-analyses is not reliable because they included studies with inconsistent results, preventing the generalizability of pooled estimates of risk or benefit.

We believe that our multicenter study provides consistent and generalizable evidence demonstrating the beneficial effects of UDT surveillance. The use of UDT did not reduce the number of patients

Table 3. Hemodialysis Access Surveillance Evaluation study subgroup analysis and interactions

Variable	Control group	Surveillance group	Difference (95% confidence interval)	P value ^a	P value ^b
Number of patients (total 436)	207	229			
Thrombotic events per patient (Poisson rate)	0.227	0.122	-0.104 (-0.184 to -0.026)	0.012	
Subgroups					
Gender					0.145
Female (n = 156)	0.237	0.188	-0.049 (-0.194 to 0.095)	0.620	
Male (n = 279)	0.223	0.087	-0.136 (-0.23 to -0.042)	0.006	
Type of vascular access					0.370
AVG (n = 62)	0.516	0.194	-0.323 (-0.619 to -0.026)	0.052	
AVF (n = 369)	0.173	0.107	-0.066 (-0.143 to 0.011)	0.117	
Age, years					0.284
> 63 (210)	0.181	0.114	-0.067 (-0.171 to 0.037)	0.281	
≤ 63 (226)	0.275	0.129	-0.145 (-0.265 to -0.026)	0.021	
Ethnicity					0.203
Hispanic (n = 227)	0.185	0.163	-0.022 (-0.133 to 0.089)	0.810	
Other (n = 116)	0.236	0.098	-0.138 (-0.289 to 0.013)	0.108	
Diabetes mellitus					0.753
Yes (n = 274)	0.223	0.111	-0.112 (-0.21 to -0.014)	0.032	
No (n = 159)	0.243	0.141	-0.102 (-0.24 to 0.036)	0.196	
Peripheral vascular disease					0.269
Yes (n = 59)	0.107	0.129	0.022 (-0.153 to 0.197)	1.0	
No (n = 372)	0.249	0.123	-0.126 (-0.214 to -0.037)	0.007	
Coronary artery disease					0.392
Yes (n = 108)	0.204	0.153	-0.052 (-0.213 to 0.109)	0.682	
No (n = 326)	0.237	0.112	-0.125 (-0.217 to -0.034)	0.009	
Hypertension					0.199
Yes (n = 368)	0.232	0.110	-0.122 (-0.208 to -0.036)	0.006	
No (n = 64)	0.216	0.222	-0.006 (-0.239 to 0.227)	1.0	

^aP value from 2-sample Poisson rate difference control and surveillance.

^bP value for interaction to assess for homogeneity.

experiencing a first thrombotic event ($P = 0.073$; Table 2) nor the time to the first thrombectomy procedure ($P = 0.149$; Figure 1); however, trends revealed numerical benefits in the surveillance group compared with the control group in these secondary outcomes, consistent with the significant benefit in the primary outcome of the rate of thrombotic events. Additionally, a numerically lower number of catheters was needed in the surveillance group (9 catheters) compared with the control group (11 catheters) ($P = 0.65$) with a lower proportion of patients to time to first catheter placement ($P = 0.62$; Figure 2). We believe the reason for less need for catheter placement in the surveillance group was the timely delivery of a thrombectomy procedure in the study patients. The HASE study has shown that monthly UDT surveillance did not result in a statistically significant increase in the number of total angiographic procedures. This contradicts the findings of previous studies.²⁵ One explanation is that the use of a monthly questionnaire that is carefully looking for clinical indicators of AV access dysfunction in addition to at least once per month AV access monitoring by qualified personnel may have led to higher than average detection of subtle clinical findings and, subsequently, a referral for further evaluation by angiogram. This may have influenced both the total number of procedures and, at the same time, the statistical value of UDT surveillance as well.

The HASE study has several strengths that we believe have a significant impact. The first is that it is the largest randomized clinical trial evaluating the value of UDT flow measurement monthly surveillance on thrombotic events. Additionally, this is a multicenter trial with representative demographic distribution of the ESRD population in the United States, and, thus, its results are generalizable. The limitations of the HASE study are that it did not enroll the targeted number of patients and therefore was not powered to show a significant benefit of UDT flow measurement, particularly in secondary outcomes such as first thrombotic events. Additionally, this study did not have the resources and aims to evaluate the hospitalization rate or cost analysis and to evaluate long-term AV access survival due to the duration of the study follow-up. Therefore, although the HASE study has shown that monthly surveillance using UDT flow measurement has resulted in a lower per-patient and per-visit thrombosis rate compared with the control group, further research looking into cost-effective analysis of surveillance programs and their effects on the hospitalization rate and long-term AV access survival is still very much needed.

DISCLOSURE

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Registration: <https://clinicaltrials.gov/>. ClinicalTrials.gov Identifier: NCT02376361.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

CONSORT Checklist.

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