

Comparison of Clinical Assessment With Ultrasound Flow for Hemodialysis Access Surveillance

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Hypothesis: Organized clinical assessment of hemodialysis access is as useful a surveillance tool as ultrasound flow measurements in preventing access thrombosis.

Design: Cohort analysis comparing a dialysis unit evaluated using ultrasound flow measurements with another unit evaluated clinically.

Setting: University-affiliated community program with private and health maintenance organization dialysis units.

Patients: One hundred patients in each unit were enrolled. Patients who were unavailable for follow-up or died within the first 30 days of enrollment were excluded from further analysis.

Intervention: Angiograms were obtained in the Transonics Doppler ultrasound system (Transonics Systems Inc, Ithaca, New York) cohort if graft flow was less than 600 mL/min, fistula flow was less than 450 mL/min, or flow decreased more than 25%, and in the clinical co-

hort if there was a change in the access appearance, change in the bruit, or a sharp increase in venous resistance.

Main Outcome Measures: Primary and secondary patencies of the hemodialysis access were analyzed for each cohort. Subset analysis was obtained for synthetic grafts and native fistulas. Procedures were assessed for each cohort.

Results: The patients in the clinical cohort had similar primary patency (1199 days) as in the Transonics cohort (1162 days) ($P = .92$). Angiographic procedures were also similar, with 56% of all patients having none. The mean number of procedures was 0.56 per patient in the Transonics cohort and 0.48 in the clinical group ($P = .48$).

Conclusion: An organized clinical assessment, using a formal tracking tool, is equal to ultrasound flow measurements as a surveillance method to prevent hemodialysis access thrombosis.

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ONGOING SURVEILLANCE OF hemodialysis access has become the standard of care. In the early years of hemodialysis treatments, assessment of a graft or fistula was accomplished by physical examination and occasional recording of venous and arterial pressures from the dialysis machine. If there was a marked change in the access on examination or a sudden or major change in the machine-measured pressures, staff in the dialysis unit might notify the surgeon or nephrologist. This process was not well organized. During the last 15 years, an increased number of testing methods have been developed to evaluate the function of the access and the adequacy of the dialysis treatment and there has been a realization that function and adequacy can be related.¹⁻⁵ These surveillance techniques are an attempt to preclude or forestall access thrombosis, which can interfere with a patient's dialysis schedule, prevent attainment of the full dialysis prescription, and possibly shorten the viability of the access. Organized testing of static⁶ and dynamic^{7,8} venous resistance, kinetic modeling,⁹ and ultrasonographic^{10,11} and flow measure-

ments^{12,13} has been used alone and in various combinations to evaluate grafts and fistulas. These are noninvasive tests, a prime directive for surveillance techniques. The most widely used direct test of hemodialysis access surveillance is the Transonics Doppler ultrasound system (Transonics Systems Inc, Ithaca, New York),¹³⁻¹⁵ which uses an ultrasound dilution method to determine flow. Other techniques use thermal dilution, optical dilution, or direct ultrasound evaluation of the access. Most of these techniques require a skilled technician, and results are operator-dependent. Some groups have questioned the need for these tests, citing their inaccuracies,^{16,17} questionable value,^{18,19} and overall costs.

We revisited the clinical evaluation of a graft or fistula while applying the more organized approach that the recent tests use. It was hoped that this evaluation would provide similar information and results while saving time and cost compared with the widely used Transonics system. The ultimate purpose of hemodialysis access surveillance is to discover a potential problem that could lead to access failure, in the least invasive and least expensive way while meeting the challenge of overlooking a prob-

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lem or overdiagnosing a potential problem for an actual problem. The gold standard for follow-up of an abnormality found during surveillance is angiography. All patients in this study having an abnormality detected on their surveillance test underwent angiography, either in the imaging department or the operating room if the access was occluded.

METHODS

Patients were divided into 2 cohorts on the basis of their dialysis unit. Full cooperation was obtained from the dialysis staff and the attending nephrologists. All grafts and fistulas were placed by our surgical group (E.S.). The clinical assessment form was developed by us with input from the dialysis personnel (**Figure 1**). This evaluation tool was used throughout the study.

Patients in unit 1 underwent bimonthly ultrasonographic studies (Transonics cohort) performed by a trained technician with 2 years of experience. Patients in unit 2 were evaluated at each dialysis session according to the criteria on the assessment form (clinical cohort).

One hundred patients were enrolled in each unit throughout September 2002. Patients who were unavailable for follow-up, lost their access, or died within 30 days of enrollment were excluded from further evaluation. There were no other selection criteria for the study.

Patients in the Transonics cohort were referred for angiography if the measured flow was less than 600 mL/min if their access was a graft or 450 mL/min if they had a fistula. For both types of access, a decrease in measured flow greater than 25% led to evaluation by a surgeon, which usually prompted angiographic evaluation.

Patients in the clinical cohort were evaluated with a "look, listen, and feel" approach. Their access was examined visually for new or enlarging pseudoaneurysms, signs of infection, ecchymoses, or changes in the access topography (dips and curves). The graft or fistula was then palpated to further assess pseudoaneurysms, topography, tenderness, and quality of the thrill or pulse. A stethoscope was used to evaluate the bruit or pulse for uniformity throughout the access. This evaluation was completed in 2 to 3 minutes. Venous and arterial resistance during dialysis were also monitored. Using the patient's usual blood flow rate, the venous and arterial resistance as measured with the dialysis machine were recorded. Any change from previous examinations for any variable was noted on the evaluation tool. If changes persisted for 3 dialysis sessions or were substantial enough to threaten the function of the access, the patient was referred to a surgeon for evaluation. Most of these patients subsequently underwent angiography.

In both cohorts, the urea reduction ratio and kinetic modeling were also observed. If there was a decrease in the urea reduction ratio or kinetic modeling with no other explanation, the access was considered possibly dysfunctional and the patient was further evaluated by a surgeon. All included patients were then followed up for 2 years or until occurrence of a terminal event such as death, access abandonment, kidney transplantation, and loss to follow-up. Outcome measures were primary patency, calculated from enrollment to access thrombosis; total primary patency, from access creation to first post-enrollment thrombosis; secondary patency, from enrollment to access abandonment or end of the study; total secondary patency, from access creation to abandonment or end of the study; and number of angiograms obtained, thrombectomies, access revisions, and total procedures per access, from the start of the study to completion or other end point.

All data were entered into a database (Excel; Microsoft, Redmond, Washington) from the source documents (Transonics

Systems Inc data sheets and the clinical evaluation tool) and then transferred to a computer statistics program (SPSS Inc, Chicago, Illinois) for statistical analysis. Paired data were evaluated with cross-tabulation and *t* test. Grouped data were evaluated with analysis of variance.

RESULTS

There were 175 evaluable patients, 90 in the Transonics cohort and 85 in the clinical group. Ninety-six patients (54.9%) were male. Seventy-eight patients (44.6%) had diabetes mellitus. Hypertension was the cause of renal failure in 42 patients (24.0%); all other causes represented less than 10%. Fistulas were the working access in 109 patients (62.3%). Ninety-three patients (53.1%) were alive with functioning access at the end of the study. Of the remaining 82 patients, 51 (29.2%) were deceased, 8 (4.6%) underwent transplantation, 4 (2.3%) were unavailable for follow-up, and in 19 (10.9%) the index access was abandoned. The mean access age at time of enrollment in the study was 855 days. Mean primary patency was 569 days, and mean secondary patency was 670 days. Comparative demographic data are given in **Table 1**. Patients in the clinical group were older and a higher percentage had diabetes. These data approached statistical significance.

The main study outcome data are given in **Table 2**. The percentage of patients achieving primary and secondary patency at 2 years was almost identical in each cohort. There were no differences in any of the specific procedures followed or the total number of procedures per patient. The thrombectomy rate for patients in the Transonics cohort was 0.13 per patient per year vs 0.09 per patient per year in the clinical cohort ($P = .24$). Ninety-eight patients (56%) required no procedures to maintain the access, with equal distribution between the cohorts. Analysis of variance was used to determine the effect of diabetes on the number of angiograms, access revisions, and thrombectomies in each group; no difference was found ($P = .7$). Similar findings were noted for age ($P = .58$). Total access duration (from creation to end point) was not different between the groups, with mean primary patency of 1424 days ($P = .70$) and mean secondary patency of 1522 days ($P = .76$). Kaplan-Meier life tables were calculated for primary patency (**Figure 2**) and secondary patency (**Figure 3**) from creation of the access to the end of the study. There was no difference between the 2 arms of the study. For all outcome variables observed, there were no statistical differences between these cohorts for the 2 years of the study and the 7 years of follow-up of the involved accesses.

COMMENT

Maintenance of the hemodialysis access has been a major challenge in patients receiving hemodialysis. Access occlusion leads to disruption of dialysis treatments, possible failure to achieve dialysis prescription, the need for a procedure to open the access, and the possibility of the patient requiring a catheter. Catheterization is fraught with problems including higher morbidity and mortality. Multiple studies have suggested the need for access

REQUEST FOR SURGICAL CONSULTATION

Patient: _____

Dialysis: M/W/F T/Th/S

Time: AM/Mid/PM

Access:	Fistula	Graft	Long-term catheterization	PD catheterization
Location:	Arm	Leg	IJ	Subclavian vein
Side:	Right	Left		

Is patient taking warfarin sodium (Coumadin) or clopidogrel bisulfate (Plavix): Yes/No

Most recent INR: _____ Date drawn: _____

BP preren: _____ mm Hg Lowest BP: _____ mm Hg Usual BP: _____ mm Hg

DIALYSIS HISTORY

Current

BFR: _____ VP: _____ AP: _____ Kt/V: _____ URR: _____ Date: _____

Access flow monitoring: _____

Previous month:

BFR: _____ VP: _____ AP: _____ Kt/V: _____ URR: _____ Date: _____

Access flow monitoring: _____

2 Months ago:

BFR: _____ VP: _____ AP: _____ Kt/V: _____ URR: _____ Date: _____

Access flow monitoring: _____

CONSULTATION FOR:

- | | | |
|---------------------------------|--------------------------|--------------------------|
| _____ Problems with cannulation | _____ Extremity swelling | _____ Prolonged bleeding |
| _____ Pseudoaneurysm | _____ Pain in extremity | _____ Hematoma |
| _____ Possible steal syndrome | _____ Infiltration | _____ Infection |

Comments: _____

To be completed by consulting office

Physician plan:

Figure 1. Consultation form. M/W/F indicates Monday/Wednesday/Friday; T/Th/S, Tuesday, Thursday, Saturday; AM, morning; Mid, midday; PM, night; INR, international normalized ratio; BP, blood pressure; IJ, internal jugular; BFR, blood flow rate; VP, venous pressure; AP, arterial pressure; Kt/V, kinetic modeling; URR, urea reduction rate.

Table 1. Demographic Data^a

Variable	Transonics ^b Cohort (n = 90)	Clinical Cohort (n = 85)	P Value
Age, y	59.5	63.5	.10
Male sex	52.0	48.0	.80
Patients with diabetes mellitus	38.0	52.0	.06
Fistula	49.5	50.5	.50
Duration of access, d	864	846	.87

^aValues are given as percentage unless otherwise indicated.

^bTransonics indicates Transonics Doppler ultrasound (Transonics Systems Inc, Ithaca, New York).

Table 2. Study Results

Variable	Transonics ^a Cohort	Clinical Cohort	P Value
Primary patency, %	68	67	.90
Secondary patency, %	90	88	.70
No. of angiograms obtained	26	26	.50
No. of access revisions	12	7	.50
No. of thromboses	12	8	.24
No. of procedures per patient	0.56	0.48	.48

^aTransonics indicates Transonics Doppler ultrasound (Transonics Systems Inc, Ithaca, New York).

surveillance,^{1,3,9,20} but few have completed a prospective study to clearly document this. Some have questioned the value of surveillance.²¹⁻²³ Many articles have addressed the various studies used to forecast a decrease in access flow or thrombosis.⁶⁻¹⁵ The National Kidney Foundation Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines (http://www.kidney.org/professionals/kdoqi/guidelines_updates/doqi_uptoc.html) recommend surveillance and suggest some of these techniques. No particular strategy is favored. Dialysis access surveillance in some form has become the standard of care. Most comparative studies use the Transonics Doppler ultrasound system flow measurements as the standard from which to evaluate other surveillance methods.^{13,14} This program has appropriate sensitivity while correlating well with angiography.

Some centers have established a surveillance program based on clinical findings^{24,25} but did not compare it with other testing methods. We evaluated an organized clinical surveillance program and assessed whether its efficacy matched a Transonics ultrasound program. These prospective cohorts were similar in all aspects except for the testing methods. Although the clinical group included more older patients and more patients with diabetes, analysis of variance showed no difference in outcomes in these patients compared with the Transonics cohort.

Some recommend determining blood flow with the Transonics system every month,^{12,26} whereas some centers assess this flow every 2 months. Inasmuch as surveillance can only forecast the likelihood of a thrombosis in the ensuing 6 to 8 months,^{2,27} the rationale for bimonthly examinations seems sound. The Kidney Disease Outcomes Quality Initiative guideline for decreas-

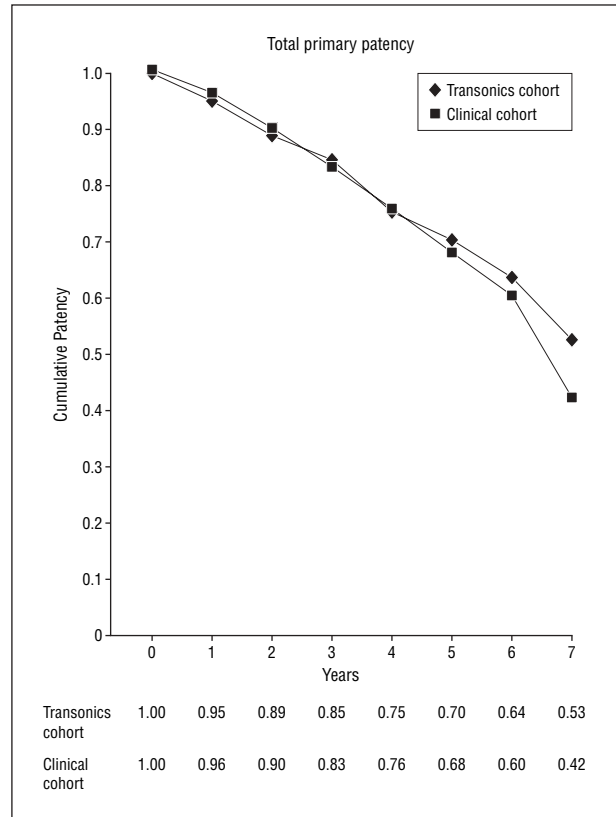


Figure 2. Kaplan-Meier primary patency curves. Transonics indicates Transonics Doppler ultrasound (Transonics Systems Inc, Ithaca, New York).

ing the thrombectomy rate to 0.5 per patient per year has readily been achieved in the clinical group, with the rate for all procedures (thrombectomy, revision, and angiography) only 0.48 per patient per year.

Data on the consultation form (Figure 1) provide the surgeon with all the information needed to assess the next step for managing a troublesome access. It also focuses the dialysis staff in their evaluation at the start of a dialysis session. The assessment takes only 2 to 3 minutes to perform. However, this unit was integral in the development of this tool and was dedicated in performing a quality evaluation. Whether this can be repeated in other units is unclear.

This study did not evaluate the relative costs of the 2 cohorts. Training personnel to conduct and evaluate the Transonics tests; purchase and amortization, or rental of the device; and the cost of additional personnel to perform the test can vary widely among dialysis units. Similarly, the cost in time to perform a clinical assessment can differ. What is clear from this study is that the efficacy of an organized clinical assessment program as a surveillance tool for hemodialysis access is equal to that of the Transonics system flow measurements.

CONCLUSIONS

Hemodialysis access surveillance with current techniques is effective in forecasting the risk of thrombosis in the ensuing 6 months. There clearly is room for improvement, but the institution of a surveillance program with any method has been an improvement over random surveil-

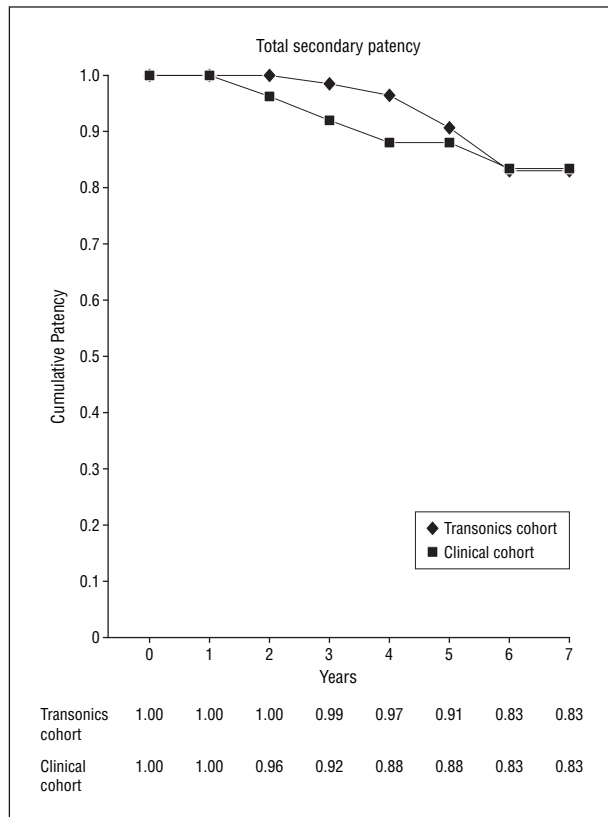


Figure 3. Kaplan-Meier secondary patency curves. Transonics indicates Transonics Doppler ultrasound (Transonics Systems Inc, Ithaca, New York).

lance. Clinical assessment, as outlined in Figure 1, is usually performed in most dialysis units but not in an organized fashion with data recorded. Our approach merely collates these data and applies them to a simple algorithm to determine the need for further testing. An interested physician or access coordinator needs to be involved to add judgment and provide the final decision as to whether to pursue additional imaging. Most methods have associated costs such as purchasing of equipment, training of personnel, and time to perform the test. Clinical assessment involves only time and its attendant costs. However, this study has shown that both methods of surveillance are equivalent. The Kidney Disease Outcomes Quality Initiative guidelines were easily met with this approach. For those units that wish to use a method of access surveillance that puts organization to procedures already performed at most dialysis centers and not rely on a single test, clinical assessment can be efficacious and reliable.

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