Hemodialysis

2019 KDOQI Guidelines & Hemodialysis Surveillance





2019 KDOQI & HD Surveillace (DL-100-hb) Rev B 2023

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Acknowledgments

Twenty-five years ago, Transonic[®] pioneered two measurement technologies for use during hemodialysis. Transit-time ultrasound technology, pioneered by Transonic founder Cornelis Drost, was used to verify true delivered blood from the dialysis pump. Ultrasound dilution technology, developed by Nikolai Krivitski, Ph.D., D.Sc., was employed to measure vascular access flow, recirculation, and cardiac function during hemodialysis. These on-the-spot measurements revolutionized hemodialysis management in end-stage renal disease (ESRD) patients undergoing hemodialysis.

We gratefully acknowledge the National Institutes of Health who, through significant financial assistance, helped support the development of these measurement modalities.

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A. 2019 KDOQI Guidelines Life-Plans

The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) provides evidence-based guidelines for hemodialysis vascular access intended to assist multi-disciplinary practitioners' care for chronic kidney disease patients and their vascular accesses.

Three years in development, the recently released 2019 Update of the KDOQI Clinical Practice Guideline for Vascular Access offers a different approach to vascular access care than in the past. These Guidelines emphasize a more patient-focused approach and recommend development of an End-Stage Renal Disease (ESRD) Life-Plan that takes each patient's individual needs and preferences into consideration when choosing an access. The Guidelines also call for planning proactively for the likely complications and remediations of a current access. Along with a Life-Plan, the Guidelines also include new topics such as guidance on vascular access choice, new targets for arteriovenous (AV) fistulas and grafts and central venous catheters, management of specific complications, and renewed approaches to some older topics such as surveillance.

The Guidelines readdress some of the practices previously considered "Best Practices." This paradigm shift in emphasis away from recommendations of standardized "Best Practices," such as encouraging a "Fistulas First" approach, now urge providers to think, during planning the first access, not only about what type of access should be first, but what type of accesses will follow. In other words, the updated Guidelines call for a customized approach for each patient that includes a map of care for the present and into the future - a Life-Plan.

A. Customized Life-Plans cont.

The Guidelines call for the planning for dialysis modalities and vascular accesses over the course of the patient's life to ensure that future needs are always being considered. For instance, a patient may initiate hemodialysis with peritoneal dialysis (PD), but then receives a kidney transplant. If the kidney transplant fails, the patient may then transition to an in-center hemodialysis facility, while becoming trained for home hemodialysis. Such forward planning can have many benefits, including helping preserve vessels needed for successful future AV access creation and use, and avoiding unnecessary procedures and complications.

Summary

The 2019 Update of KDOQI Guidelines has refocused recommending creation of a patient's Life-Plan first that incorporates his or her corresponding access needs. Addressed are the preparation for and creation of vascular accesses, the care and management of each type of vascular access, and the prevention and treatment of complications. While continuing to emphasize high-quality standards, there is a greater emphasis on the need for improved training and application of physical vascular access monitoring, and a corresponding de-emphasis on the need for AV access surveillance.

The Guidelines present primary targets for use in tracking performance reasonably. The primary target is that each patient has a regularly updated Life-Plan designed with his/her goals in mind to achieve the most suitable dialysis access type and with consideration of changes in circumstances. Its goal is to support practices that will lead to the ideal vascular access that is reliable, complication-free, able to deliver prescribed dialysis, and is suitable for each patient's needs.

B. Physical Exam - A Primary Component of a Life-Plan

Physical Examination (Surveillance)

13.1 KDOQI recommends regular physical examination or check of the AVF / AVG, by a knowledgeable and experienced health practitioner, to detect clinical indicators of flow dysfunction of the AVF. (Conditional/Strong Recommendation, Moderate Quality of Evidence)

A primary component in the 2019 KDOQI proposed Life-Plan is to have a regular physical examination or check of an arteriovenous fistula (AVF) or graft (AVG) by a knowledgeable and experienced healthcare practitioner in order to detect clinical indicators of flow dysfunction in an AVF or AVG.

Indeed, a thorough physical exam is fundamental to and presages all diagnoses and treatment for all diseases. Nevertheless, two aspects to this recommendation might be considered.

First is the phrase "by a knowledgeable and experienced healthcare practitioner." Is it feasible to have every patient at every dialysis session at every center examined by a "knowledgeable, experienced health practitioner," that implies a nurse or doctor? While in European countries and Canada where hemodialysis is generally administered by a nurse, this might well be practical. However, in the United States, hemodialysis delivery is frequently, if not always, relegated to dialysis technicians because nursing resources are under staffed and there is constant high staff turnover. This recommendation of having a physical exam administered by a "knowledgeable, experienced health practitioner" is challenging for US clinics, the largest providers of hemodialysis clinics are reluctant to add staff and/or tools that are not mandated.

The second point for consideration is that a physical exam is totally subjective. It relies on the skill and experience of the person administering the exam. Is one clinical impression sufficient? In practice, most medical health professionals seek to back up their clinical impressions with secondary tests (ECGs, CT scans, blood work etc.).

In the case of hemodialysis, many clinics rely on quantitative Transonic ultrasound dilution flow measurements to corroborate their first clinical impressions and inform them in their decision making.

The ultimate goal of any Guideline is to provide clinicians with tools that provide insight into the physical condition of a patient in order to be able to make the best decisions for their individual patients. Is a physicial exam alone sufficient to accomplish this?

C. Surveillance Complements a Physical Exam

Surveillance to Facilitate Patency

13.4-13-5 There is inadequate evidence for KDOQI to make a recommendation on routine AVF or AVG surveillance by measuring access blood flow, pressure surveillance, or imaging for stenosis, that is additional to routine clinical surveillance, to improve access patency.

Note: In other words, monitoring of vascular access is primary, while surveillance findings are supplementary, and action should not be based solely on surveillance findings.

This 13.4-13-5 Guideline first states that there is inadequate evidence to recommend the measurement of access blood flow by ultrasound dilution or other surveillance measures. As a provider of vascular access flow measurement tools for more than 25 years, Transonic takes issue with this statement. Ample evidence demonstrates that Transonic flow measurements provide objective data in mLs/min, of vascular access flow, true pump flow, recirculation in AV grafts, fistulas and catheters and cardiac function. Two powerful randomized controlled trials, the American HASE Study (pages 9-13), and Dr. Ines Aragoncillo's Spanish study (pages 14-16), "Adding access blood flow surveillance reduces thrombosis and improves arteriovenous fistula patency: a randomized controlled trial," and the many studies cited in the annotated Bibliography on pages 23-26 attest to the value of Transonic quantitative measurements.

In today's US dialysis environment where nursing resources are under staffed and clinics, looking at their bottom line, are not adding additional tools due to cost, there is no impetus to provide clinicians with supplementary resources or tools such as the Transonic HD03 Hemodialysis Monitor.

In practice, the 2019 KDOQI Guidelines have given for-profit clinics carte blanche to provide the bare minimum of tools for their healthcare providers and patients. Staff and their patients deserve more. They deserve to have healthcare providers supplied with the quantitative information from surveillance tools to back up clinical impressions, so that they can choose the best treatments for customized KDOQI Life-Plans.

The last part of the statement, "Surveillance findings are supplementary and action should not be based solely on surveillance findings" rings true. Transonic measurements have always been considered to be supplementary and action to intervene on an vascular access should not be based solely on surveillance findings. All clinical indications and assessments, of which flow is simply one component, should always be considered by the nephrologist. Secondly, flow measurement surveillance will not improve access patency by itself. Surveillance is one objective tool in a clinician's arsenal to help guide clinical decision making.

D. Transonic HD03 Surveillance

Vascular Access Flow: Transonic vascular access surveillance measures access flow directly for an immediate snapshot of access function. Trending of these measurements over time provides data to indicate flow-limiting conditions anywhere in the circuit. A drop in access flow may signal formation of a stenosis in time for proactive minimally invasive intervention by the dialysis care team (see pages 20-21). Of note: the Achilles Heel in intervention is actually the lack of practice by most physicians outside of the University setting, to quantitatively measure access flow before, during and post intervention. Due to this, many interventions fail due to lack of adequate measurements and quality controls of the intervention. One cannot verify intervention success based on subjective metrics and thus, many studies have pointed to a failure of intervention success.

Dialysis Adequacy: The Hemodialysis Monitor also can be used to optimize dialysis delivery by measuring true delivered pump blood flow and recirculation in AV fistulas, grafts and catheters to ensure optimal delivery of a KT/V prescription (pages 18-19). By measuring

D. Transonic HD03 Surveillance cont.

true delivered blood flow through dialysis tubing and then comparing this true flow to the pump's reading, any flow limiting cause can be identified and corrected on the spot. The Hemodialysis Monitor also detects and quantifies access recirculation in AV fistulas, grafts and catheters. Measurements in catheters (page 19) are used to establish a maximum dialysis pump setting before recirculation occurs. Known flow and recirculation values can also be used to adjust the length of dialysis, identify flow restrictions and failing CVCs, and determine the best connections between a CVC and the blood lines.

ESRD Life-Plans Supported by HD03 Measurements

Examples of customized ESKD Life-Plans for vascular access with inclusion of Transonic HD03 measurements include the following: a pediatric patient, a young patient, an elderly patient, an acute start patient and a home dialysis patient.

Pediatric Patient: 6-yr-old Girl	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	Congenital cause of kidney disease, CKD not yet on dialysis, family wants to be evaluated for living related donors, left handed	 PD Living donor transplant if donor is identified; how- ever, if not, place on the transplant wait list Hemodialysis 	1. PD catheter 2. Transplant 3. RC-AVF (right)	 * Follow closely, life- long anticipated * Flexibility required as Life-Plan may change * Life-Plan must consider multiple modalities & opti- mize access

Transonic Measurement Clinical Application once RC-AVF is the active access:

• Routine clinical examination (look, listen, feel, arm elevation, and augmentation) should be used regularly as part of the pre-cannulation process.

• Transonic Access Flow measurements are intended to be utilized in conjunction with the clinical examination to detect/confirm indications of access dysfunction.

ESRD Life-Plans Supported by HD03 Measurements cont.

Young Patient: 28-year-old male	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	Alport syndrome with rapid CKD progression requiring dialysis initiation, multiple abdomen surgeries related to a trauma, R handed, plays guitar/drums in a band.	 HD outpatient Evaluation for living related Tx or Tx waiting list Return to HD if needed to return to dialysis post-transplant 	 Lower arm endovascu- lar AVF (left) BC-AVF (left) if endovas- cular AVF fails 	 * Endovascular AVF preferred to reduce steal syndrome risk or mega fistula to avoid impairment of his ability to play guitar or drums. Reduce physi- cal disfigurement from a surgical AV access. * Follow closely, lifelong anticipated

Transonic Measurement Clinical Application:

- Routine clinical examination (look, listen, feel, arm elevation and augmentation) should be used regularly as part of the pre-cannulation process.
- Transonic Access Flow measurements can be used with with a clinical examination to detect/confirm indications of access dysfunction.
- A potential for cardiac overload exists if the Access Flow is > 1600mL/min. Evaluate patient for signs and symptoms of high-output cardiac failure if Access Flow reaches the high range.

Elderly Patient 80-year-old female	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	CDM, HTN, CHF, vision issues, CKD rapidly advancing with multiple hospitalizations, lives with her husband, active but does require the use of a walker, R handed	1.Hemodialysis outpatient	 Forearm early cannulation AVG Secondary upper arm AVF 	 * Patient likely has a limited life expec- tancy * Focus on AV access and limiting CVC dependency vs. preserving sites for future access

Transonic Measurment Clinical Application:

- Routine clinical examination (look, listen, feel, arm elevation, augmentation) should be used regularly as part of the pre-cannulation process.
- Transonic Access Flow measurements can be used with a clinical examination to detect/confirm indications of access dysfunction.
- A potential for cardiac overload exists if the Access Flow is > 1600mL/min. Evaluate patient for signs and symptoms of high-output cardiac faulire if Access Flow reaches the high range.

ESRD Life-Plans Supported by HD03 Measurements cont.

Acute Start Patient: 45-year-old male crash-lands on HD	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	Acute start with no prior treatment of CKD; Urgent placement of HD catheter for hemo- dialysis, lives alone and lacks family support, R handed	 Acute HD HD outpatient Evaluate for transplant and placement on the transplant waiting list 	 Tunnel Cuffed Catheter RC-AVF (left) Transplant while maintaining the vascular access if needed for return to hemo dialysis 	 * Follow closely, life- long anticipated * Flexibility required as Life-Plan may change * Life-Plan must consider multiple modalities and optimize dialysis access

Transonic Measurement Clinical Application:

• Utilize Delivered Flow and Recirculation as part of the hemodialysis catheter algorithm for "On The Spot" catheter adequacy check and adjustment of blood flow rate and or catheter connection configuration as needed. Utilize this in both the acute hospital setting and outpatient hemodialysis facility.

Once the RC-AVF is created and being utilized as the dialysis access:

- The routine clinical examination (look, listen, feel, arm elevation and augmentation) should be used regularly as part of the pre-cannulation process.
- The Transonic Access Flow measurements are intended to be utilized in conjunction with the clinical examination to detect/confirm indications of access dysfunction.

On hemodialysis for 3 years including home HD for past 2 years. CKD caused by neph- rotoxic chemotherapy drugs to treat previous colon cancer, R handed.1. Home Hemodi- alysis1. RC-AVF* Maximize the lifes- pan of her current AVF if fails or move up the arm for new AVF0. hemodialysis for 3 years including home HD for past 2 years. CKD caused by neph- rotoxic chemotherapy drugs to treat previous colon cancer, R handed.1. Home Hemodi- alysis1. RC-AVF* Maximize the lifes- pan of her current AVF if fails or move up the arm for new AVF0. Note: or move up the arm for of a new AVF above the current RC location.1. Home Hemodi- alysis1. RC-AVF	Home HD Patient: 55-year-old female	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
		On hemodialysis for 3 years including home HD for past 2 years. CKD caused by neph- rotoxic chemotherapy drugs to treat previous colon cancer, R handed.	 Home Hemodialysis Waiting to reach 5 plus years post cancer to be evaluated for a kidney transplant 	 RC-AVF Revision of her current AVF if fails or move up the arm for new AVF 	 * Maximize the lifespan of her current RC-AVF * Preserve R arm vessels above the current RC-AVF for any required revision for creation of a new AVF above the current RC location.

Transonic Measurement Clinical Application:

- Routine clinical examination (look, listen, feel, arm elevation, and augmentation) should be used regularly as part of the pre-cannulation process.
- Transonic Access Flow measurements are intended to be utilized in conjunction with the clinical examination to detect/confirm indications of access dysfunction.
- A potential for cardiac overload exists if the Access Flow is > 1600mL/min. Evaluate patient for signs and symptoms of high-output cardiac faulire if Access Flow reaches the high range.



II. The Hemodialysis Access Surveillance Evaluation (HASE) Study -

A multi-center randomized clinical trial of hemodialysis access blood flow surveillance compared to standard of care

Background

AV access stenoses are found in most thrombosed AV accesses and are the leading cause of AV access loss. The purpose of monthly blood flow surveillance with ultrasound dilution technology (UDT) is to detect stenotic lesions in AV access circuits early so that they can be treated pre-emptively with percutaneous transluminal angioplasty (PTA) before low dialysis adequacy, high recirculation and/or AV access thrombosis occur. Nevertheless, routine use of AV access surveillance for early detection and management of stenosis to reduce thrombosis rate remains a subject of lively debate.

Study Objective

The objective of this multi-center randomized clinical trial of hemodialysis access blood flow surveillance compared to standard care was to examine the utility of AV access blood flow UDT surveillance for early detection of stenotic lesions and the effect of pre-emptive PTA on AV access thrombosis. A primary hypothesis was that blood flow surveillance would decrease the rate of access thrombosis and surveillance would increase the time to the first thrombotic event increasing the number of angioplasties, decreasing the number of thrombectomies, and decreasing the rate of tunnelled hemodialysis catheter placement.

II. HASE Study cont.

Study Methodology

Four-hundred thirty-six (436) ESRD patients were randomized for a multi-center, prospective, clinical trial conducted between 2014 and 2019 at three dialysis sites: Miami Miller School of Medicine with 45% (196) of the total enrollees; California Kidney Specialists, San Dimas, California with 34% (147) of the enrollees and Albany Medical Center with 21% (93) of the enrollees in the study.

Two groups of patients were created from the enrollees: a Standard of Care Group (Surveillance Group) that included 229 patients who underwent monthly UDT surveillance during the first 90 minutes of dialysis and a Standard of Care group of 207 patients who did not undergo surveillance and were the control. Eighty-six percent of surveillance group patients had an AVF as compared to 85% of patients in the control group. Seventy-seven percent of patients in the surveillance group had an upper arm-based AV access compared to sixty nine percent in the control group. Both groups were followed for the duration of the two year study.

The study protocol included:

- One monthly physical examination of the AV access by a trained care provider;
- A monthly questionnaire to detect the following clinical indicators:
 - Prolonged bleeding;
 - Upper extremity edema;
 - Difficulty with AV access cannulation;
 - Aspiration of clots during cannulation,
 - Aneurysmal formation that met the criteria for referral;
 - Access pressures that prevent normal hemodialysis machine operation;
 - Unexplained lower than target monthly Kt/V;
 - Recirculation rate of more than 10%.
- Corroboration by the Transonic HD03 Hemodialysis Monitor of high recirculation rates recorded by the urea method.



II HASE Study cont.

Study Results

Fifty-eight of 229 surveillance patients and 90 of 207 control patients completed for totals of all 24 visits 3278 visits for the surveillance group and 3353 visits for the control group. Three control patients and two surveillance patients left the study after a surgical revision. Patients with blood flow of less than 600 mL/min in AVGs, less than 500 mL/min in AVFs, or if AV access blood flow declined by more than 25% over four months in patients with blood flow above 1000 mL/min, were referred for further evaluation with an AV access angiograhy.

Statistically Significant Difference in Number of Thrombotic Events

Twenty-seven (27) thrombotic events occurred in the surveillance group while 37 thrombotic events occurred in the control group during the follow-up period creating a statistically significant difference in thrombotic events per patient in the surveillance group compared to the control group (0.122 vs. 0.227, difference -0.104 p=0.012).

No Significant Difference in Total Number of Procedures Between Groups

A secondary outcome was that there was no statistically significant difference in total number of procedures between the two groups, irrespective of whether thrombectomy procedures were included or excluded.

No Significant Differences in Rate or Time to First Thrombotic Event There were no statistically significant differences in the rate of or time to first thrombotic event.

No Significant Differences in the Number of Catheters Placed due to Thrombosis A numerically lower number (9) of catheters were needed in the surveillance group compared to control group (11) (p=0.65) with lower proportion of patients for time to first catheter placement (p=0.62).

II. HASE Study cont.

Study Conclusions/Discussion

The primary finding of the HASE study was that it demonstrated that monthly surveillance of AV fistulas using ultrasound dilution flow measurement resulted in a lower per patient and per visit thrombosis rate as compared to the control group. Secondly, the total number of procedures per patient was not significantly increased, regardless of whether thrombectomy procedures are included or excluded from the analysis. The investigators conjecture that this might be explained by the inclusion of a monthly questionnaire in the study, in addition to at least once per month AV access surveillance, that carefully looked for clinical indicators of AV access dysfunction. This questionnaire may have led to higher than average detection of subtle clinical findings and subsequently, a referral for further evaluation by angiogram. Thus, inclusion a questionnaire in the study may have influenced both the total number of procedures and the statistical value of UDT surveillance.

The investigators state that their multi-center study provides consistent evidence that demonstrated the beneficial effects of UDT surveillance. While the use of UDT did not reduce the number of patients experiencing a first thrombotic event (p=0.073), nor the time to the first thrombectomy procedure (p=0.149), trends revealed numerical benefits in the surveillance group compared to control group in secondary outcomes, consistent with the significant benefit in the primary outcome of the rate of thrombotic events.

Furthermore, the investigators believe the reason for less need for catheter placement in the surveillance group was the timely delivery of a thrombectomy procedure in study patients.



II. HASE Study cont.

Study's Limitations

An important limitation of the HASE study is that it did not enroll the targeted number of patients and, therefore, was not powered to show significant benefit of UDT flow measurement, particularly in secondary outcomes such as first thrombotic events. Secondly, the study lacked the resources and objectives to evaluate hospitalization rate, cost analysis, and to evaluate long-term AV access survival due to duration of study follow-up.

Study Strengths

- 1. The HASE study's strength is that it is the largest (436 patients) randomized clinical trial evaluating the value of UDT flow measurement monthly surveillance on thrombotic events.
- 2. Secondly, its results can be generalized because the study was multicenter with a representative demographic distribution of the ESRD population in the US.

Reference:

Salman L, Rizvi A, Contreras G, Manning C, Feustel PJ, Machado I, Briones PL, Jamal A, Bateman N, Martinez L, Tabbara M, Vazquez-Padron RI, Asif A, "A multicenter rand-omizedclinical trial of hemodialysis access blood flow surveillance compared to standard of care - The Hemodialysis Access Surveillance Evaluation (HASE) Study," Kidney International Reports (2020), doi:https://doi.org/10.1016/j.ekir.2020.07.034. (Transonic Reference # HD11823AH

III. Adding Access Blood Flow Surveillance Reduces Thrombosis and Improves Arteriovenous Fistula patency: - A randomized clinical trial

Background

Although stenosis is recognized as the main cause of arteriovenous fistula (AVF) failure, it is still unclear whether surveillance based on vascular access blood flow (QA) alone enhances AVF function and longevity.

Study Objective

The objective of this Spanish, multi-center¹ randomized clinical trial was to conduct a three-year follow-up controlled, open-label study that compared QA-based surveillance and pre-emptive repair of subclinical stenosis with standard monitoring/surveillance techniques in prevalent mature AVFs.

1Madrid, Spain: Nephrology Unit, Hospital Gregorio Marañón, Clínica Fuensanta, Hemodialysis Unit, Nephrology Unit, Hospital Infanta Sofía; Preventive Medicine Unit, Hospital Clínico; Hospital Universitario La Princesa; Clínica Dialcentro, Hemodialysis Unit; Clínica Los Enebros, Hemodialysis Unit. 1Barcelona, Spain: Corporació Sanitària i Universitària Parc Taulí, Hospital de Sabadell; Nephrology Unit, Hospital de Mollet, Mollet del Vallès.



II. Aragoncillo Study cont.

Study Methodology

AVFs were randomized into two groups: a Control group (n = 104) which had surveillance based on classic alarm criteria detected by physical examination, and a QA group (n = 103) in which access flow (QA) was measured quarterly by Transonic ultrasound dilution technology and Doppler ultrasound [M-Turbo®], in addiion to the classic monitoring used in the control group.

The criteria for intervention in the QA group was a 25% reduction in QA, QA<500 mL/min or significant stenosis with hemodynamic repercussion (peak systolic velocity [PSV] more than 400 cm/sc or PSV pre-stenosis/stenosis higher than 3). Other criteria for intervention included:

- Unexplained lower than target monthly Kt/V;
- Recirculation rate of more than 10%.

The Transonic HD03 Hemodialysis Monitor was also used to corroborate of high recirculation rates recorded by the urea method.

Study Results

The QA group show significant reduction in the thrombosis rate

- QA group (QA) group (0.025 thrombosis/patient/year)
- Control group (0.086 thrombosis/patient/year)

There was significant improvement in the thrombosis-free patency rate (HR, 0.30; 95% CI, 0.11-0.82) and in the secondary patency rate in the QA group (HR, 0.49; 95% CI, 0.26-0.93) in the QA group.

While there was no differences in the primary patency rate between groups (HR, 0.98; 95% Cl, 0.57-1.61), the assisted primary patency was significantly higher in the QA group compared to the control group.

There was greater need for central venous catheters and more hospitalizations associated with vascular access in the control group.

Finally, total vascular access-related costs were higher in the control group (€227.194 vs. €133.807) versus the QA group.

II. Aragoncillo Study cont.

Study Conclusion

QA-based surveillance combining Doppler ultrasound and ultrasound dilution reduces the frequency of thrombosis, is cost effective, and improves thrombosis free and secondary patency in autologous AVF.

Study's Strength

To the author's knowledge, this is the first randomized controlled trial that shows secondary patency rate improvement using a combination of ultrasound dilution and Doppler ultrasound technologies. The thrombosis rate findings and thrombosis-free AVF survival rates are consistent with the Tessitore 2004 randomized controlled trial "Can blood flow surveillance and pre-emptive repair of subclinical stenosis prolong the useful life of arteriovenous fistulae? A randomized controlled study."

References:

Aragoncillo I, Abad S, Caldés S, Amézquita Y, Vega A, Cirugeda A, Moratilla C, Ibeas J, Roca-Tey R, Fernández C, Macías N, Quiroga B, Blanco A, Villaverde M, Ruiz C, Martín B, Ruiz AM, Ampuero J, de Alvaro F, López-Gómez JM. **Adding access blood flow surveillance reduces thrombosis and improves arteriovenous fistula patency: a randomized controlled trial.** J Vasc Access. 2017 Jul 14;18(4):352-358. doi: 10.5301/jva.5000700. Epub 2017 Apr 20. PMID: 28430315. (Transonic Reference # HD11190A)

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Tessitore N, Lipari G, Poli A, Bedogna V, Baggio E, Loschiavo C, Mansueto G, Lupo A. **Can blood flow surveillance and pre-emptive repair of subclinical stenosis prolong the useful life of arteriovenous fistulae? A randomized controlled study**. Nephrol Dial Transplant. 2004 Sep;19(9):2325-33. doi: 10.1093/ndt/gfh316. Epub 2004 Jul 27. PMID: 15280529. (Transonic Reference # HD407A)



IV. HD03 Surveillance

A Host of Measurements That Confirm Clinical Findings, Optimize Hemodialysis, Avert Thrombosis and Execute KDOQI Life-Plans

Dialysis Adequacy in AV Grafts and Fistulas



Measure Delivered Blood Flow

The Transonic[®] Hemodialysis Monitor measures true delivered blood flow through dialysis tubing using "Gold Standard" transit-time ultrasound technology. By comparing true delivered blood flow to the pump's reading, any flow limiting cause such as small needle diameter or incorrect needle placement can be identified on the spot and corrected.

Measure Access Recirculation

recirculation, each of which can compromise

The Hemodialysis Monitor is used to optimize dialysis adequacy by measuring true delivered pump blood flow and

delivery of a KT/V prescription.

With a single infusion of saline, the Transonic Hemodialysis® Monitor detects and quantifies access recirculation, a late indicator of a failing access. Because Transonic[®] ultrasound dilution technology can separate cardiovascular recirculation form cardiopulmonary recirculation, 0% Recirculation can be measured and quantified. Measurement of recirculation will:

- Identify inadvertent reversal of blood lines (see box below);
- Confirm proper needle placement;
- Confirm 0% recirculation.

Dialysis Adequacy in Central Venous Catheters (CVCs)



Catheter Adequacy

End-Stage Renal Disease (ESRD) patients will likely undergo dialysis administered through a CVC. Whether emergent and temporary, acute or chronic, CVCs will often underdeliver dialysis due to:

- a discrepancy between a dialyzer's pump setting and its true delivered flow;
- and/or the presence of recirculation during dialysis delivery.

HD03 Surveillance of Catheter Dose Delivery

Dialysis delivery through CVCs have two potential pitfalls:

- 1. A tissue flap can block the lumen of the catheter's arterial entry port, impeding flow and causing a severe drop in dialysis dose delivery. An HD03 measurement of true delivered blood flow identifies drops in dose and can be corrected on the spot.
- 2. Recirculation will likely occur due to the close proximity of the catheter's arterial entry and venous return ports. Recirculation in catheters can be identified by the HD03 Monitor and optimized on the spot to provide the most

efficient dialysis possible.

Transonic's HD03 Hemodialysis Monitor Measurements Optimize **Dialysis Catheter Delivery by:**

- Helping to establish a maximum dialysis pump setting before recirculation occurs:
- Using known values for flow and recirculation to adjust the length of dialysis;
- Identifying flow restrictions;
- Finding the best catheter configuration between the catheter blood lines (regular or reversed);
- Identifying failing catheters through high recirculation rates.

Vascular Access Flow in AV Grafts and Fistulas

Access flow is the quintessential vital sign for an AV Access. Insufficient flow causes underdialysis. Still lower flow invites thrombosis. Too much flow can lead to cardiac problems with associated morbidities.

Transonic Hemodialysis Monitors, Flow/dilution Sensors use the "Krivitski Method[®]" to measure access flow directly for an instant snapshot of access function and detection of flow limiting problems wherever they might occur within a vascular access circuit.

An access patency record can be generated by measuring vascular access flow routinely and trending the results over several months. A drop in access flow may signal formation of a stenosis in time for proactive minimally invasive intervention.



Krivitski Method[®]: Reversed line position for access recirculation measurement. Saline injection is still made into the venous line which is now the upstream line.

Fistula and Graft Access Flow Interpretation

200	400	600	800	1000	1200	1400	1600	1800	2000	2200
Jppe	er Arm A	VF (elbow	and abo	ve)						
200	400 600	800	1000	1200	1400 10	500 18 (00 2000	2200	2400	2600
AV G	iraft (forea	arm loop gi	raft)							

as flow decreases (indicated by color progression from blue to purple)

Action: Consider Clinical Examination & Imaging **Expected Access Flow Range** Expected flow range is ideal. However, a sudden drop of 25% in this range may signal a potential onset of stenosis.

Monitoring. If 25% Decrease Occurs.

Consider Clinical Exam & Imaging

Probable risk for Cardiac Failure as flow increases (indicated by color progression from yellow to red)

Action: Evaluate the patient for signs and symptoms of high output cardiac failure.

Notes:

• Actual flow levels for AV fistula and graft patients should be customized by the nephrologist.

If Flow Is Steady, Continue

Action:

- A clinical examination (look, listen, feel, arm elevation and augmentation) should be used routinely as part of the pre-cannulation process.
- Transonic access flow measurements are intended to be utilized in conjunction with a clinical examination to detect/confirm indications of access dysfunction.
- Snuffbox or endovascular fistulas may have a lower access flow range depending on the location of the anastomosis and the vessel's outflow configuration.
- Upper arm AV fistulas typically have a higher access flow range due to the larger artery size.
- A potential for cardiac overload exists at flow >1600-3000 mL/min. Evaluate patient for signs and symptoms of high-output cardiac failure.



Theory & Validations (UDT, TTFM)

Ultrasound Dilution (UDT)

Krivitski NM, **"Novel Method to Measure Access Flow during** Hemodialysis by Ultrasound Velocity Dilution Technique," ASAIO 1995; 41(3): M741-M745. Theory and bench validation of access flow measurement by ultrasound velocity dilution. Reversal of dialysis lines creates a zone of mixing in the vascular access, allowing the use of dilution technique for access flow measurement. Data show that access flow can be accurately measured by sound velocity dilution technique.

Depner TA, Krivitski NM, MacGibbon D, **"Hemodialysis Access Recir**culation (Rc) Measured by Ultrasound Dilution," ASAIO J 1995; 41(3): M749-M753. "The data suggest that the ultrasound dilution method is both sensitive and accurate."

Depner TA, Krivitski NM, "Clinical Measurement of Blood Flow in Hemodialysis Access Fistulae and Grafts by Ultrasound Dilution," ASAIO J 1995; 41(3): M745-M749. "These data show that blood flow in peripheral arteriovenous grafts and fistulas can be measured accurately during hemodialysis using ultrasound velocity dilution."

Bosman PJ, Koomans HA et al, "Access flow measurements in hemodialysis patients: in vivo validation of an ultrasound dilution technique." J Am Soc Nephrol. 1996 Jun;7(6):966-9. " Measurements correlated well with flow rates determined by magnetic resonance angiography and by a technique based on intra-access flow-pressure curves. ...Access flow can be measured easily, noninvasively, and reliably by the ultrasound dilution device.... The method requires little investment in time making it superior to other methods."

Krivitski NM, MacGibbon D, Gleed RD, Dobson A, **"Accuracy of** Dilution Techniques for Access Flow Measurement During Hemodialysis," AIKD 1998; 31(3): 502-508. "An error in access flow measurement of 20% or more arises from the use of flow reading taken from pump setting rather than a measured flow. The discrepancy between the real flow and pump setting is attributable to needle size, vascular access conditions, or pump calibration."

Krivitski NM, Depner TA, "Cardiac output and central blood volume during hemodialysis: methodology," Adv Ren Replace Ther. 1999;6(3):225-232. "CO and CBV can be routinely and reliably measured during hemodialysis if precautions are taken to avoid specifically identified sources of error."

Kislouchine VV, Dean DA, **"Validation of a Novel Ultrasound** Dilution Method to Measure Cardiac Output during

Hemodialysis, " ASAIO J 1996; 42(5): M906-M907. "Cardiac output measured by ultrasound velocity dilution during hemodialysis is in good agreement with well established, but invasive, transit time and pump standards."

Transit-time Ultrasound (TTFM)

Nikiforov UV, Kisluchine VV, Chaus NI, "Validation of a New Method to Measure Cardiac Output during Extracorporeal Detoxification," ASAIO J 1996; 42(5) M903-M905. "Data suggest agreement between the ultrasound dilution technique and thermodilution. Ultrasound dilution is preferable in patients undergoing extracorporeal detoxification when pulmonary artery catheterization is not required or dangerous.

"Drost CJ, "Volume Flow Measurement System," U.S. Patent # 4,227,407, Cornell Research Foundation, Inc., Ithaca, NY, October 14, 1980. "Patent for transit-time ultrasound flow measurements: outlines a device and method for direct measurement of volume flow of fluids through a tube, using an interferometric transit-time technique based on an electric signal which is proportional to fluid flow and is, to a high degree, independent of flow profile, conduit geometry, and alignment of the conduit within the probe."

Drost CJ, "Homogeneous Full Flow Illumination to Ultrasonic Systems," Proceedings of the 31st Annual Conference of Engineering in Medicine and Biology, Bethesda MD: Alliance for Engineering in Medicine and Biology 1978; 20: 183. "If the signal acquired in ultrasonic blood flow measuring systems could be made to represent the full flow rather than a (spatially often ill defined) portion of one, it is obviously a step closer to instantaneously measuring the total flow independent of flow profile and vessel geometry."

Drost CJ, "Vessel Diameter-Independent Volume Flow Measurements Using Ultrasound," Proceedings of San Diego Biomed. Symposium, San Diego CA: San Diego Biomed. Soc. 1978; 17: 299-302, 1978. "Theoretical background for a volume flow measuring technique in which volume flow is measured directly, independent of vessel diameter, vessel shape, flow profile or vessel aluignment within the nonconstrictive probe."

Hemisch W, "Blood Flow during Cardiovascular Surgery: Methodological, Technical and Practical Considerations," Gefäßchirugie, Springer-Verlag, 1996. "Comparison of Doppler, electromagnetic and transit-time ultrasound technologies noting that transit time ultrasound is the only method able to measure volume flow inside artificial vascular prostheses."

Randomized Controlled Trials: Vascular Access Flow

Predictive Power of Arteriovenous Access Flow Measurements

Salman L et al, "A multicenter randomized clinical trial of hemodialysis access blood flow surveillance compared to standard of care - The Hemodialysis Access Surveillance Evaluation (HASE) Study," Kidney International Reports (2020), "The HASE study demonstrated that monthly surveillance using UDT flow measurement has resulted in lower per patient and per visit thrombosis rate as compared to the control group."

Aragoncillo I *et al*, "Adding access blood flow surveillance reduces thrombosis and improves arteriovenous fistula patency: a randomized controlled trial," J Vasc Access. 2017; 18(4): 352-358. "QA-based surveillance combining Doppler ultrasound and ultrasound dilution reduces the frequency of thrombosis, is cost effective, and improves thrombosis-free and secondary patency in autologous AV."

Ashoor IF, Hughson EA, Somers MJ, "Arteriovenous access monitoring with ultrasound dilution in a pediatric hemodialysis unit." Blood Purif. 2015;39(1-3):93-8. "Thrombosis rate dropped from 13.5 per 100 patient-months on HD during the baseline period to 3.5 per 100 patient-months on HD during the surveillance period. Ultrasound Dilution surveillance is very sensitive in detecting hemodynamically significant stenosis and can decrease AV access thrombosis rates."

Park HS, Kang SH, Chung BH et al, "Effect of intradialytic change in blood pressure and ultrafiltration volume on the variation in access flow measured by ultrasound dilution," Kidney Res Clin Pract. 2013; 32(1):16-20. "Variation in access flow during HD is relatively small. Decreased blood pressure is a risk factor for variation in access flow measured by ultrasound dilution. In most patients whose blood pressures are stable during HD, the access flow can be measured at any time during the HD treatment."

Chan KE, Hakim RM et al, "Access survival amongst hemodialysis patients referred for preventive angiography and percutaneous transluminal angioplasty," Clin J Am Soc Nephrol. 2011 Nov; 6(11):2669-80. "Huge statistical study (41, 132 Medicare patients, 1,342 Fresenius facilities, 48 states) determined, "The benefits of PTA interventions are most seen in newer accesses or accesses with insufficient flow."

Maoz D, Reinitz R, Schneiderman J et al, "Hemodialysis graft flow surveillance with prompt corrective interventions improves access long-term patency," Clin Nephrol. 2009 Jan;71(1):43-9. "Stringent flow surveillance policy coupled with prompt intervention has proven effective in maintaining AVG long-term patency."

van Loon M, Tordoir JH et al, "Implementation of a vascular access quality programme improves vascular access care." Nephrol Dial Transplant. 2007 Jun;22(6):1628-32. "(24 center, 2300 patients) An AV Access Care Quality Improvement Plan is worthwhile to improve dialysis patients' care and access morbidity." Tessitore N et al, "Adding access blood flow surveillance to clinical monitoring reduces thrombosis rates and costs, and improves fistula patency in the short term: a controlled cohort study," Nephrol Dial Transplant 2008 23:3578-3584. "Adding Qa surveillance to monitoring in mature AVFs is associated with a better detection and elective treatment of stenosis, and lower thrombosis rates and access-related costs."

Wijnen E, van der Sande F et al, "Impact of a quality improvement programme based on vascular access flow monitoring on costs, access occlusion and access failure," Nephrol Dial Transplant. 2006 Dec;21(12):3514-9. "A quality improvement programme based on periodical access flow measurement reduced the number of acute vascular access failures due to thrombotic events and also significantly reduced health care costs in patients with AVG, but not in patients with AVF."

Lopot F et al, "Comparison of different techniques of hemodialysis vascular access flow evaluation," J Vasc Access. 2004 Jan-Mar;5(1):25-32. "Ultrasound Dilution measurements were used as the gold standard to compare other surveillance methodologies. "The very high reproducibility seen in UD, both for measurements at the same extracorporeal blood flow (QB) and for measurements at two different QB justifies its current status of a reference method in vascular access flow."

Lok CE, Bhola C, Croxford R, Richardson RM, "Reducing vascular access morbidity: a comparative trial of two vascular access monitoring strategies," Nephrol Dial Transplant. 2003 Jun;18(6):1174-80. "A three-year study, 300-400 patients. Low flow rates detected using Transonic monitoring were associated with increased thrombosis, while stenosis detected using Duplex ultrasonography was not a strong predictor of incipient thrombosis."

Goldstein SL, Allsteadt A, **"Ultrasound Dilution Evaluation of Pediatric Hemodialysis Vascular Access,"** Kidney Int 2001; 59: *Study supports the use of monthly measurement to prevent access thrombosis in children receiving HD.*

McCarley PB, Ikizler TA et al, "Vascular Access Blood Flow Monitoring Reduces Access Morbidity and Costs," Kidney Int 2001; 60:1164-72. "Vascular access blood flow monitoring along with preventative interventions should be the standard of care in chronic hemodialysis patients. ... The comprehensive cost is markedly reduced due to the decreased number of hospitalizations, catheters placed, missed treatments, and surgical interventions."

Sands JJ, Jabyac PA, Miranda CL, Kapsick BJ, **"Intervention based** on monthly monitoring decreases hemodialysis access thrombosis," ASAIO J. 1999 May-Jun;45(3):147-50. "We believe that monthly access flow measurement will ensure the lowest incidence of thrombosis and decrease the cost of access maintenance."

Randomized Controlled Trials: Vascular Access Flow

Predictive Power of Arteriovenous Access Flow Measurements, Cont.

Neyra NR, Ikizler TA, May RE, Himmelfarb J, Schulman G, Shyr Y, Hakim RM, "Changes in access flow over time predicts vascular access thrombosis," Kidney Int 1998; 54: 1714-1719. "There is a 13.6-fold increase in the relative risk of thrombosis for accesses with more than 35% decrease in vascular access blood flow. Study prospectively determined that measurement of blood flow plays an important role in evaluation and detection of PTFE grafts at higher risk of thrombosis"

May RE, Himmelfarb J, Yenicesu M et al, "Predictive measures of vascular access thrombosis: A prospective study," Kidney Int 1997;52:1656-1662. Three-center study of 170 patients over six months. "The blood flow by Dilution (for grafts) was the best predictor of thrombosis within the subsequent three months. Multi-variate analysis showed a significantly increasing risk of thrombosis with decreasing access blood flow."

Sands J, Glidden D, Miranda C, "Hemodialysis access flow measurement. Comparison of ultrasound dilution and duplex ultrasonography." ASAIO J. 1996 Sep-Oct;42(5):M899-901. "Measurement of hemodialysis access flow by ultrasound dilution was essentially equivalent to that obtained by duplex ultrasound

Dialysis Adequacy

Zero Vascular Access Recirculation - A New Reality

MacDonald JT Sosa MA, Krivitski NM, Glidden D, Sands JJ, "Identifying A New Reality: Zero Vascular Access Recirculation Using Ultrasound Dilution," ANNA J 1996; 23(6): 603-608. "A new method, ultrasound dilution, avoids these problems and supports a new clinical reality-zero access recirculation."

Alloatti S, Molino A, Bonfant G, Ratibondi S, Bosticardo G M, "Measurement of Vascular Access Recirculation Unaffected by Cardiopulmonary Recirculation: Evaluation of an Ultrasound Method," Nephron 1999; 81(1) 25-30. "AR determination by USM, avoiding misleading interferences with CPR, is a rapid, easy, and noninvasive method to routinely exclude a potential cause of reduced dialytic efficiency."

Basile C, Ruggieri G, Vernaglione L, Montanaro A, Giordano R. "A comparison of methods for the measurement of hemodialysis access recirculation," J Nephrol. 2003;16(6):908-913. "AR in autogenous radiocephalic wrist AVFs was zero when measured by means of the USM."

Twardowski ZJ, Van Stone JC, Haynie JD, "All Currently Used Measurements of Recirculation in Blood Access by Chemical Methods are Flawed Due to Intradialytic Disequilibrium or Recirculation at Low Flow," Am J Kid Dis 1998; 32(6): 1046-1058. "The ultrasound dilution method usually gave lower values than the chemical methods, most likely because of overestimation of recirculation by chemical methods."

Lindsay RM, Bradfield E, Rothera C, Kianfar C, Malek P, Blake PG.I, "A Comparison of Methods for the Measurement of Hemodialysis Access Recirculation and Access Blood Flow Rate," ASAIO J 1998; 44: 62-67. "TRANS and HDM appear equal as far as accuracy and repeatability of measurements."

Discrepancy between Prescribed & Delivered HD Pump Flow

Sands J, Glidden D, Jacavage W, Jones B, **"Difference between delivered and prescribed blood flow in hemodialysis,"** ASAIO J. 1996;42(5):M717-M719. "*Delivered and prescribed blood flow* (*QB*) was compared during 208 hemodialysis treatments using the Transonic hemodialysis monitor. Delivered QB averaged 205.6, 300.6, 384.3 (p < .0001), and 467.7 cc/min (p < .0001) at pump settings of 200, 300, 400, and 500 cc/min."

Depner TA, Rizwan S, Stasi TA, **"Pressure effects on roller pump blood flow during hemodialysis**," ASAIO Trans. 1990;36(3):M456-M459. "Blood pump meter readings greater than 400 ml/min were usually inaccurate because of low Pa."

Kelber J, Delmez JA, Windus DW. "Factors affecting delivery of high-efficiency dialysis using temporary vascular access," Am J Kidney Dis. 1993;22(1):24-29. "In spite of the change in arterial line pressure, measured blood flow rate increased appropriately at all set blood flows and with all catheter sites studied."

Teruel JL, Fernández Lucas M, Marcén R, Rodríguez JR, López Sánchez J, Rivera M, Liaño F, Ortuño J, "Differences between blood flow as indicated by the hemodialysis blood roller pump and blood flow measured by an ultrasonic sensor," Nephron. 2000;85(2):142-147. doi:10.1159/000045647. "The blood flow indicated by the dialysis blood roller pump is always greater than the delivered blood flow, and this difference is in turn conditioned by the negative pressure induced by the blood roller pump in the arterial blood line."

Ward RA, "Blood Flow Rate: An Important Determinant of Urea Clearance and Delivered Kt/V," Adv Ren Replace Ther 2001; 6(1): 75-79. (HD193A) " For quality assurance purposes, actual blood flow rates should be determined by correcting nominal blood flow rates for pressure effects using empirical relationships or by using an ultrasonic flow meter. Because a poorly functioning blood access may further reduce the effective blood flow rate, blood access performance should also be monitored regularly."

Mehta HK, Deabreu D, McDougall JG, Goldstein MB. **"Correction of discrepancy between prescribed and actual blood flow rates in chronic hemodialysis patients with use of larger gauge needles,"** Am J Kidney Dis. 2002;39(6):1231-1235. "This study shows that the use of larger gauge needles can significantly increase d-BFR and PRU as a result of changes in arterial and venous pressures, resulting in a significantly increased dialysis dose at no additional cost."

Dialysis Adequacy

Measurements of Recirculation and Delivered Flow in Catheters

Twardowski ZJ, Haynie JD, "Measurements of hemodialysis catheter blood flow in vivo," Int J Artif Organs. 2002;25(4):276-280. " Pressures & blood flows were measured at pump speeds from 50 to 500 ml/min in increments of 50 ml/min with lines in normal configuration. Blood flow was measured continuously using ultrasound. The correlations between pressures and flows are not linear."

Level C, Lasseur C, Chauveau P, Bonarek H, Perrault L, Combe C, "Performance of twin central venous catheters: influence of the inversion of inlet and outlet on recirculation." Blood Purif. 2002;20(2):182-188. "Thus, measurement of the effective blood flow and recirculation by ultrasound velocity should be included in quality monitoring and maintenance."

Leblanc M, Bosc JY, Vaussenat F, Maurice F, Leray-Moragues H, Canaud B, "Effective Blood Flow and Recirculation Rates in Internal Jugular Vein Twin Catheters: Measurement by Ultrasound Velocity Dilution," Am J Kid Dis 1998; 31(1): 87-92. TwinCath delivers an effective Qb of nearly 375 mL/min when Qb is set at 400 mL/min on most dialysis machines. Mean R in TwinCath varies between 5% and 11% for Qb within the range of 200 to 400 mL/min.

Leblanc M, Bosc JY, Paganini EP, Canaud B. "Central venous dialysis catheter dysfunction," Adv Ren Replace Ther. 1997;4(4):377-389. Several recent studies confirm that short femoral catheters recirculate significantly more than is desirable. Well functioning and nonreversed internal jugular and subclavian venous catheters have, in general, recirculation rates less than 5%.

Little MA, Conlon PJ, Walshe JJ, "Access Recirculation in Temporary Hemodialysis Catheters as Measured by the Saline Dilution Technique," Am J Kid Dis 1998; 36(6): 1135-1139. Using ultrasound dilution technology the researchers found "that temporary femoral catheters shorter than 20 cm are associated with increased recirculation rates...when dialysis dose delivery is a priority, locating the temporary catheter in the internal jugular vein is an advantage."



Transonic Systems Inc. is a global manufacturer of innovative biomedical measurement equipment. Founded in 1983, Transonic sells "gold standard" transit-time ultrasound Flowmeters and Monitors for surgical, hemodialysis, pediatric critical care, perfusion, interventional radiology and research applications. Transonic® also provides pressure and pressure volume systems, laser Doppler Flowmeters and telemetry systems.

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