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The Hemodialysis Access Surveillance Controversy Continues

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See Clinical Research on Page 1937

An English essayist William Hazlitt (1778–1830) once said, "When a thing ceases to be a subject of controversy, it ceases to be a subject of interest."

A vascular access is essential to provide life-sustaining hemodialysis treatment to patients with end-stage kidney disease. The preferred vascular access remains to be an arteriovenous fistula (AVF); however, it is often complicated by failure to mature in the early stages and in the long-term by the development of stenosis, thrombosis, and aneurysm/pseudoaneurysm formation. The pathophysiology for stenosis involves neointimal hyperplasia and poor outward remodeling of the vessel wall.[1] The luminal narrowing over time causes a reduction in blood flow, which at a critical juncture results in access thrombosis. Early detection of a failing vascular access can trigger a timely referral for appropriate intervention and possibly the prevention of a thrombotic event. The dialysis access complications account for 12% to 25% of hospital admissions. More importantly, a dysfunctional vascular access remains a leading cause for morbidity requiring multiple interventions, which consumes a significant portion of the health care budget. In 2013, the Centers for Medicare and Medicaid Services paid $2.8 billion for dialysis access–related services.[2]

The basic principle of performing vascular access monitoring and surveillance is to identify a dysfunctional access for appropriate intervention and ultimately to minimize the disruption of dialysis therapy. The terms monitoring and surveillance were introduced and defined by Kidney Disease Outcomes Quality Initiatives clinical practice guidelines.[3] Monitoring refers to using physical examination along with clinical and biochemical abnormalities to detect vascular access dysfunction. Surveillance involves using special equipment to evaluate and identify access dysfunction. The objective for surveillance tests is to measure dialysis access blood flow,[S1] dynamic or static access venous pressure or to evaluate anatomic abnormalities using the ultrasound dilution method, pressure monitoring tools, or Doppler ultrasonography,[S2] respectively. The Kidney Disease Outcomes Quality Initiatives clinical practice guidelines recommend monitoring the vascular access during the maturation phase and before each dialysis treatment, including empowering the patient to participate in his or her care. The role of vascular access surveillance to predict stenosis has remained controversial and has been debated now for almost 2 decades.[S3,S4]

In this issue, Salman *et al.*[4] have reported a multicenter, prospective randomized clinical trial using a complementary surveillance plus monitoring technique to assess vascular access in the surveillance group (n = 229) compared with standard of care alone in the control group (n = 207). The surveillance group underwent monthly access blood flow measurement using the ultrasound dilution technique. The standard of care monitoring involved at least once a month detailed physical examination of the AVF by a trained dialysis provider and a monthly survey to assess the clinical indicators as outlined by Kidney Disease Outcomes Quality Initiatives clinical practice guidelines. A randomized group of 436 prevalent hemodialysis patients with either AVF or an arteriovenous graft were included in the study and followed for a 2-year period. The rigorous exclusion criteria included a history of a single episode of thrombosis, age more than 80 years or less than 18 years, active malignancy, and life expectancy of less than 6 months. The study was completed by less than 50% of the enrolled patients (90/207 [43%] in the control group and 58/229 [25%] in the surveillance group). The number of thrombotic events encountered during the study period were 27 and 37 in the surveillance group versus the control group, respectively. There was a

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statistical difference in the number of thrombotic events per patient (0.122 vs. 0.227, $P = 0.012$) as well as per visit (0.0085 vs. 0.014, $P = 0.037$) between the surveillance group and the control group, respectively. The secondary outcomes of the number of endovascular interventions (0.991 vs. 0.981, $P = 0.95$) and central vein catheter placements (0.039 vs. 0.053, $P = 0.65$) were not statistically different between the surveillance group and the control group, respectively.

The controversy over the utility of dialysis access surveillance in predicting the risk for a thrombotic event has remained unresolved. The surveillance method ideally should consistently detect a stenotic lesion with reasonable accuracy. Of the various methods available for access surveillance, measuring blood flow and access pressure are the most widely used parameters in clinical practice. However, other factors such as the cannulation technique, variation in hemodynamics during hemodialysis, and the number of stenotic segments within an access circuit can all influence both flow and pressure within an access circuit.[5,6]

The access surveillance controversy began when early small cohort observational studies with a historical control group reported a significant reduction in thrombotic events.[S5] These studies were questioned with equally small randomized controlled trials reporting contradictory outcomes. The major limitations to draw any definitive conclusion from these studies were attributed to single-center trials, which were nonrandomized and often had a mix of AVF and arteriovenous graft accesses.[7]

In the past decade, there have been several randomized controlled trials with AVF alone. The studies supporting the benefits of using access surveillance to predict the risk of thrombosis continue to be small with variable access blood flow (750–900 ml/min) cutoff points for intervention. The studies were further difficult to analyze because some of them used surveillance alone, and others used the surveillance method with a clinical indicator to intervene. The definitions used for access dysfunction were not standardized either. A systematic review of 4 studies with AVF ($n = 310$) found a lower risk of access loss (relative risk 0.5; 95% confidence interval, 0.29–0.86) and thrombosis (relative risk 0.5; 95% confidence interval, 0.35–0.71) between the active surveillance group and the clinical monitoring group, respectively.[8] However, 3 of the 4 studies included in the analysis were performed at the same center. The indication to intervene was based on the change in access flow from baseline, which was variable (>20% to >25%) in these studies, making it impossible to draw any consistent conclusion. In their randomized controlled trial, Aragoncillo *et al.*[9] ($n = 199$) compared a clinical monitoring group (control) with a clinical monitoring plus ultrasound dilution flow surveillance test performed every 3 months (surveillance) with a 1-year follow-up period. The thrombosis events were higher in the control group compared with the surveillance group (0.099 thrombosis/patient vs. 0.022 thrombosis/patient, respectively; $P = 0.03$). However, the overall circuit patency was no different at a cost of increased therapeutic interventions.[8]

In their study, Salman *et al.*[4] have improved on some of the drawbacks of the past studies. They have standardized the control group and compared it with a surveillance protocol that is an add-on to the routine clinical monitoring protocol, but, yet again, the surveillance protocol is different from previous studies. The ultrasound dilution blood flow test is performed at monthly intervals unlike the 3 monthly intervals in the previous randomized controlled trial.[S6] The study also highlights the challenges of recruiting less than 50% of patients and hence was not powered to answer the following elusive question: Is ultrasound dilution access blood flow assessment better than clinical monitoring alone to predict a thrombotic event? At best, the study demonstrates the complementary role played by the surveillance method of access blood flow measurement to clinical monitoring in a real-life situation.

The 2019 Kidney Disease Outcomes Quality Initiatives vascular access update redefines "access flow dysfunction" as clinically significant abnormalities in AVF flow or patency secondary to underlying stenosis or thrombosis. The 2006 guidelines included all pathologies of AVF abnormality including aneurysm/pseudoaneurysm and "steal" syndrome in the definition. The 2019 guidelines emphasize the complementary role of surveillance to routine clinical monitoring and do not recommend preemptive endovascular intervention in the absence of any clinical indicators. Furthermore, in the presence of clinical indicators of dysfunction, timely and confirmatory imaging with possible intervention within 2 weeks is considered acceptable. The importance of a careful individualized approach is stressed, keeping the

overall end-stage kidney disease goals of care ("ESKD Life-Plan").[10]

In the coronavirus disease 2019 era, the dialysis vascular access evaluation becomes even more complicated because maintaining a "safe distance" and remote working protocols makes frequent clinical examination of a vascular access difficult to accomplish. Should we be looking at methods to performing surveillance tests using remote technology? The surveillance controversy continues as we are nowhere close to finding a superior alternative to bedside monitoring of dialysis vascular access.

> "No great advance has ever been made in science, politics, or religion, without controversy."
>
> —Lyman Beecher

DISCLOSURE

TJV is on the Advisory Board of Vasc-Alert. EA declared no competing interests.

SUPPLEMENTARY MATERIAL

Supplementary File (DOCX)

Supplementary References.

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