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Letter

Options for Hemodialysis Vascular Access- Should We Reconsider?

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Short Title: Rethinking Vascular Access in Hemodialysis

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The need for complication free, reliable vascular access for hemodialysis (HD) that is easy to create, use, and maintain remains unrealized. Guidelines recommend Arteriovenous fistula (AVF) as the preferred vascular access based on the observational evidence of favorable dialysis adequacy, patient survival, rates

of infections, and hospitalizations.[1] However, a significant number of patients are unable to attain mature AVF with subsequent actions that lead to stress, poor outcomes, and increased cost.

In this context, let us reflect on the dilemmas and caveats of current philosophy of vascular access choice and why a new course of action might be more desirable.

Achieving AVF in everyone is difficult

In early 2000s, only a third of prevalent maintenance HD patients in the US utilized AVF, and AV graft (AVG) and central venous catheters (CVC) were used frequently. CVC was associated with frequent thrombosis, infections, hospitalizations, poor outcomes, and cost. Fistula First Breakthrough Initiative (FFBI) was started in 2003 aiming to achieve AVF in 50% of incident patients and 40% of prevalent patients. The goal in prevalent patients was achieved and a stretch goal of 65% prevalent CVC by 2009 was established. [2] Prevalent AVF rate peaked at 68% in 2017 but could not be sustained. As of 2022, 59.3% of prevalent HD patients were using AVF, and 24.5% were using CVC.

As the AVF rates improved, CVC rates did not show significant decline by 2015 and the initiative transformed into 'Fistula First, Catheter Last'. Among incident HD patients in 2015, 60.3% had only CVC as their initial access, increasing to 74.3% in 2022. The incident AVF rate declined from 16.5% in 2012 to 12.5% in 2022 despite extensive efforts and high resource utilization.[3] Even today, over 80% of HD patients initiate HD with a CVC, and approximately 20% of prevalent patients continue using it.[3] Sustaining a high AVF prevalence remains difficult, with potential to misjudge patient preference due to AVF mandates, despite best intentions.

Benefits and risks of AVF have not been well stated

Most of the evidence supporting better outcomes with AVF/AVG as compared to CVC came from observational studies.[4] Patient-related factors, rather than the fistula itself, may account for the survival benefit attributed to AVF.[5] Patients with limited resources face significant barriers to access to quality care, including delayed nephrology referral, inability to take time off for necessary preoperative vein mapping, and poorly controlled diabetes or other cardiovascular risk factors that delay surgical clearance. A study found that patients with lower socioeconomic status have lower rates of AVF/AVG use, worse primary AVF patency, and lower rates of transition from CVC to AVF/AVG.[6] The healthcare disparities confound conclusions about relative benefits and risks of different vascular accesses and may have exaggerated poor outcomes of non AVF access.

Primary failure of AVF after creation ranges from 30% to 70% in the US.[2, 7] Attempts to 'mature' these AVF with primary failure result in more procedures, resource utilization and patient suffering. AVF needing maturation are not superior to AVG or CVC. Primary failure makes success of AVF creation, even with timely referral and surgery, to coincide with HD initiation unpredictable due to biological, logistical, social, and demographic factors.[2] Further, comparing AVF to CVC outcomes is driven by comorbidities in those who are unable to receive a mature AVF. Successful AVF creation is especially difficult in patients with comorbidities.

After maturation, AVF are not complication free either. Both AVF and AVG commonly develop aneurysms that are not only disfigurative and cosmetically unsightly but can lead to adverse clinical outcomes. Bleeding is common, including fatal bleeding from AVF/AVG in rare cases. Cannulation site bleeding can lead to anxiety and transportation issues. Steal syndrome is a well-known side effect of AVF/AVG and High output heart failure, pulmonary hypertension and right heart failure are frequently not recognized.

Management of chronic kidney disease (CKD) has undergone seismic changes

A. Demographics of End Stage Kidney Disease (ESKD) patients have shifted

Patients with ESKD are increasingly older with a multitude of comorbidities.[3] They frequently have difficulty in developing a mature AVF.[8] Interestingly, in the very initial cohort of 14 relatively young non-diabetic patients undergoing Cimino fistula creation, one patient's AVF was too small to be used, while another never matured.[9] It is biologically plausible for the older population to have a high AVF failure rate.[8] Females, and those with heart failure or PVD, also have a higher primary failure rate.[10] Not only this results in a lower AVF prevalence, a lower quality of life has been reported in elderly patients with AVF compared to those with CVCs.[10] Attempts to create an AVF in elderly is often complicated by subsequent 'maturation' procedures, and a delay in, or even failure of, maturation. In one study of 602 participants, a third of the patients required intervention for maturation or complication[11]. As mentioned, AVF that fail initially often require multiple interventions, and some are eventually abandoned, but require excessive surgeries with associated risks and cost. Therefore, many elderly and female patients may benefit from alternative access.

B. Aggressive AVF creation and maintenance have resulted in minimal benefits and higher costs

Attempts to increase AVF rates may yield diminishing gains. Individual ability to develop mature AVF is not only related to biological factors, but surgeon experience (and geographic availability), and technical variations are also important. It has been shown previously that adequate training of surgical trainees in AVF creation is limited, and surgeon availability is scarce in many areas.

AV access creation process can be significantly expensive. In one study, the estimated cost for AVF creation was \$9,388 versus \$13,539 for AVG during the year of creation.[12] Costs remained significantly higher for AVG vs. AVF for the subsequent 3 years of follow-up. In a USRDS analysis of incident dialysis patients the annualized access costs for tunneled dialysis catheter were US\$13,625, AVF US\$16,864, and AVG US\$20,961. Staying with tunneled dialysis catheter had lowest access-related costs, AVF was intermediate, and AVG had the highest cost. [13] Maintaining an AVF can also be expensive. In a retrospective study of elderly US Medicare patients initiating HD therapy from 2010 to 2011, vascular access costs per patient per year in the 2.5 years after AVF creation were between \$7,871- \$31,630. Furthermore, only 54% of AVFs were successfully used for HD.[14] The highest cost was incurred by those AVF that were never used. There will be tremendous opportunities for resource savings by delaying AVF/AVG placement until patients were closer to or had started dialysis.

C. Mandates to create AVF conflict with individual vascular access choice

Societal guidelines do not fully account for the high failure-to-mature rate for AVF, and patient centric approach was lacking in initial guidelines. The guidelines transformed into "performance metrics" via the 2012 Quality Incentive Program (QIP), which rewards centers with high AVF prevalence and penalizes those with high CVC prevalence[15]. This "one-size-fits-all" approach ignores patient comorbidities, preferences, or availability of local resources, and has unintended consequences.

D. Prediction of time to dialysis or AVF maturation remains imperfect

The KDOQI guidelines recommend access planning when the eGFR approaches 15-20 mL/min- based on expert opinion.[16] Both guidelines and QIP recommend prioritization of AVF/AVG placement ahead of dialysis initiation. Consequently, many patients with poor likelihood of maturing AVF undergo AVF creation, with subsequent secondary procedures, poor outcomes and increased costs. Also, many patients maintain

a stable, low eGFR much longer without needing dialysis. Many mature AVF are never used due to the futility of HD from comorbidities and competing risk of death.

One study demonstrated that the ESKD risk within one year for patients with CKD 4 and CKD 5 is 4.29% and 28.2%, respectively.[17] Not placing AVF in late CKD may necessitate HD initiation with a CVC, but they can be converted to AVF later with full consideration of preferences. Careful follow up and late creation of AVF may be better and create much less stress and waste from futile procedures.

E. There are better therapies to delay CKD progression

Innovation in CKD care has provided us therapies including Renin angiotensin aldosterone system (RAAS) blockers, sodium glucose transporter- 2 inhibitors, non-steroidal mineralocorticoid antagonists and glucagon like peptide- 1 agonists that can sustain patients in advanced CKD much longer without needing dialysis, making access surgery unnecessary. The utilization of these medications needs to be encouraged.[18] The medical community needs to focus on upstream delay of progression of CKD to ESKD.

F. Infection prevention in catheters has innovated

The main concern of a higher rate of blood stream infection (BSI) with CVC compared with AVF/AVG has been improving. In 2019 Dialysis surveillance report, overall BSI rate decreased by 40% between 2014 and 2019 with CVC BSI rate decreasing from 2.16 per 100 Patient-Months to 1.21 per 100 Patient-Months.[19] The reduction in the rates of CVC BSI is likely to continue with better infection prevention techniques including chlorhexidine catheter cap and intra-catheter device combined with meticulous attention to infection prevention in dialysis clinics. A recent study of catheter lock with Taurolidine/Heparin lock solution demonstrated reduction in the risk of CRBSI by 71% compared to heparin only lock solution.[20] Such innovations are likely to make CVC less undesirable in appropriate circumstances.

Patient Preference, Autonomy, and Quality of Life

Individual preferences of patients not wanting AVF/AVG must be respected. AVF/AVG cannulation can cause anxiety, pain, and depression, which negatively impact quality of life. [18] In DOPPS (2010-2011) report on access choice of US patients, CVC was preferred by 9% males, 11% black females and 17% non-black females. The most common reasons were not to be stuck with needles and not to bleed post dialysis. [21] For patients, a CVC may be more cosmetically acceptable and can avoid needle sticks, surgery, and bleeding. The type of dialysis access should be decided by the patient after thorough and unbiased consultation from health care providers. A shared decision-making process should be implemented instead of a top-down approach. After adequate vessel mapping, depending upon the availability of suitable veins and their sites, some patients can be reconsidered for PD as their choice of RRT if they don't prefer AVF/AVG or are not suitable for AVF/AVG.

The 2019 KDOQI vascular access guidelines recommended development of an “End Stage Kidney Disease Life-Plan” to tailor access to each patient’s specific clinical situation and goals.[16] It acknowledged the appropriate use of long-term CVC in certain settings. Patient choice after proper informed consent was also supported. These are welcome guidelines.

There is potential to reengineer approach to HD access

The discussion above highlights important reasons to consider a patient oriented and cost-effective paradigm of vascular access choice. Figure 1 suggests a potential preliminary approach that can be refined further with multidisciplinary discussion. Access preparation should wait if there is a low likelihood of

starting HD within 6 months, although education of choices can start at that time. An AVF/AVG can be created at a lower eGFR while progression to ESKD and initiation of HD are delayed with newer therapies. If AVF does not mature in time, HD can be initiated with a catheter with aggressive infection prevention while an AVF/AVG is created by shared decision making. In appropriate cases, a long-term catheter would also be acceptable.

Methods of accurate prediction of HD initiation and access maturation would be the key to optimizing AVF creation. Utilization of Kidney Failure Risk Equation (KFRE) in addition to eGFR cutoff may better identify patients who will progress rapidly into dialysis. One study compared referral patients based on eGFR alone vs eGFR +KFRE 2-year risk scores above 40% in 2,581 CKD patients with eGFR <20 mL/min. It showed that the patients who started hemodialysis within 2 years with an AVF/AVG increased from 49% to 58%. [22] The score has shortcomings but demonstrates that a prediction model can improve AVF/AVG utilization.

Conclusion

There has been an evolution in ESKD demographics, technology, and newer therapies to prevent CKD or delay the dialysis initiation. It is important to change our attitude towards dialysis vascular access choice and strategy to improve outcomes. There is a subset of patients which is not suitable for AVF/AVG placement and would benefit from CVC. CVC infection rates have decreased, and wider use of infection prevention techniques including antimicrobial catheter lock is likely to decrease infection rate further. We recommend respect for patient's autonomy in choosing type of dialysis access based on each person's medical conditions and personal preferences. Better selection of patients suitable for AVF/AVG who are closer to HD initiation would avoid prolonged stress and waste associated with access creation. With these changes, the kidney community can shift focus from preparing for dialysis to upstream prevention of CKD and delaying progression to dialysis. It will be important to create a new framework of choosing access and remove prevalent catheter and AVF rate mandate from Medicare's ESRD QIP. In doing so, we can achieve "the right access, in the right patient, at the right time, for the right reasons" while maintaining patient preferences.

Conflict of Interest Statement

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Author Contributions

Dr. Sijie Zheng conceptualized the commentary. Dr. Sijie Zheng and Dr. Anil Agarwal drafted the work and final approval of the version to be published. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Figure 1. Flow Diagram for AVF/AVG Referral

