Kidney Medicine

Vascular Access for Home Hemodialysis: A Perspective on Tunneled Central Venous Catheters at Home

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Expansion of home hemodialysis (HHD) provides an opportunity to improve clinical outcomes, reduce cost of care, and address the staffing challenges currently faced in caring for patients with kidney failure on replacement therapy. To increase HHD expansion, current practices and barriers to home dialysis must be examined and addressed. One such barrier is vascular access for HHD; although tunneled hemodialysis central venous catheters (CVCs) have been used for decades, physicians still hesitate to send patients home without a mature, functional arteriovenous access. An expert panel of clinicians was convened by Outset Medical, a manufacturer of hemodialysis systems, to review the literature and generate consensus recommendations regarding the use of CVCs for HHD. Consistent with the most recent Kidney Disease Outcomes vascular access guidelines, the end-stage kidney disease life plan should be created via shared decision making for modality choices, with the corresponding dialysis access individualized for the patient, and for whom a CVC may represent the most appropriate vascular access to provide HHD.

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BACKGROUND

In the early years of kidney replacement therapy, home hemodialysis (HHD) was the leading modality in the United States, with utilization as high as 90% in parts of the country.[1] Medicare expansion to cover hemodialysis (HD) services in 1973 led to proliferation of HD centers and a progressive decline in HHD to less than 1% by the late 1990s.[2] A slow resurgence of HHD began in the early 2000s and now represents 0.2%-0.3% of the prevalent dialysis population. While seemingly modest, HHD has become the fastest growing modality in the United States with a relative growth rate of greater than 55%.[3]

Numerous regulatory and environmental factors have contributed to the expansion of HHD; in response, there has been an advent of newer, more user-centric technologies to support its growth.[4,5] In 2019, the Executive Order on Advancing American Kidney Health provided incentives to expand kidney transplantation and home dialysis. Concurrently, patients with kidney failure were included into Medicare Advantage, both regulatory factors supporting greater HHD use. During the recent SARS-CoV-2 pandemic, the fragility of supply chain and nurse-intensive staffing and the increased risk of communicable disease transmission in dialysis centers were quickly exposed.[6-8] The fragility and risks inherent in many dialysis centers can be mitigated by the appropriate shift of eligible patients to HHD. Coupled with the increase in telehealth and newer home technologies that allow remote monitoring, electronic medical record integration, and data transmission, the expansion of HHD has never been more feasible.[9] HHD provides an opportunity to improve patient outcomes, lower overall cost of care, address nurse resource limitations, and provide patients with greater autonomy with the goal to improve the patient experience.

To achieve a meaningful increase in HHD, the obstacles to expansion must first be identified and addressed. First is the reality of unplanned starts and the associated lack of time to properly plan for HHD and attain a mature arteriovenous (AV) access for replacement therapy. Approximately 40% of patients initiate HD as an urgent start, and 80% of all patients, regardless of planned starts, initiate HD with a central venous catheter (CVC).[10,11] Second, there is a predominance (87%) of in-center HD as the "default" kidney replacement modality for the prevalent kidney failure population. In-center HD may not be the most appropriate modality for all patients, and many patients may be better suited for HHD. As such, a change in modality distribution must primarily consider the transition of patients from both acute and in-center environments to the home, without the accompanying dialysis access type being a barrier to decision making. Indeed, dialysis access is an important clinical decision to support the modality and the needs of the individual patient. We have learned from the well-intentioned national quality initiative, called Fistula First established in 2015, that a "one-size-fits-all" population-based approach is inappropriate for patient-centered care. Although Fistula First successfully demonstrated that clinicians could effect change on a national level, it also yielded the unintended consequence of many patients with insufficient arterial or venous anatomy undergoing repeated unsuccessful attempts at arteriovenous fistula (AVF) creation despite modest to high surgical risk and low preoperative likelihood of success yielding a significant number of "futile" AVFs (eg, never used within 2 years of creation).[12-17] As a result, the most recent Kidney Disease Outcomes Quality Initiative (KDOQI) vascular access guidelines now recommend the development of an End-Stage Kidney Disease Life-Plan for each patient that focuses on individualized modality strategy and access

needs—the vascular access choices that accompany a chosen modality/modalities, to achieve "the right access, in the right patient, at the right time, for the right reasons."[18] In this construct, patients and their physicians select modalities appropriate for the patient's medical and life circumstances, and in doing so, may appropriately opt for a tunneled CVC as longer-term vascular access, recognizing that most prior data on the risks with a tunneled CVC were derived largely from patients receiving in-center HD and subject to significant bias and confounding inherent in all observational data analyses.

A clinical workgroup was convened by Outset Medical, a manufacturer of HD systems used for both hospital and home use, to review the available data surrounding the use of tunneled CVC for HHD. The workgroup comprised clinicians and scientists with expertise in the care of patients with kidney failure, HD vascular access, and home dialysis modalities. Members reviewed the published literature, data from the United States Renal Data System (USRDS), and their own clinical experience to provide consensus recommendations on the use of tunneled CVC for HHD. Key takeaways from the workgroup discussions are provided in Table 1.

TUNNELED HD CVCS FOR KIDNEY REPLACEMENT THERAPY

According to the USRDS Annual Data Report, approximately 83% of patients commenced maintenance HD with a CVC in 2020.[11] Despite a sizeable fraction of patients undergoing AVF creation within the first 90 days of HD initiation, there is a continued dependence on CVC because AVF maturation often takes longer than 90 days. It is common to require multiple procedures before an AVF is sufficiently developed to sustain cannulation without infiltration or severe bruising, and sometimes even with multiple procedures, AVFs are not usable for dialysis.[12,13] Indeed, the most common complications of AVF creation include thrombosis and failure to mature, resulting in abandonment.[19] A recent meta-analysis reported that only 26% of AVFs placed are mature after 6 months, and 21% are abandoned without use.[19]

Studies have demonstrated that AVF failure can be particularly high in subpopulations, such as patients with frailty, over 65 years old, those with small vessel size or diseased /damaged vessels, and patients with more comorbid conditions. These same subpopulations demonstrate lower penetration of AVFs and AV grafts (AVGs) (together referred to as AV access), likely reflecting the overall lack of suitability of these patients for AV access.[14,15,18] Among patients with AV access created after dialysis initiation, older patients, patients with diabetes, and those located in the United States were more likely to suffer primary AV access failure and require secondary intervention, leading to significant increases in morbidity and costs of care.[20,21]

In a pilot trial of AVF versus AVG creation in older patients started on HD with a CVC, patients with an AVF underwent an average of 5 interventions, and those with an AVG underwent an average of 2 interventions before successful cannulation.[22] For these reasons, and particularly in high-risk patients, it is not reasonable to delay referral to HHD until an AVF is mature. Such a delay likely obligates the patient to in-center HD and can reduce the likelihood that the patient (and care partner) will ultimately perform HHD, as suggested by the <4% of incident patients on in-center HD who transition to home dialysis (combined peritoneal dialysis [PD] and HHD) at 90 days.[10]

In the prevalent HD population, CVC use has remained consistent since 2012 at approximately 20%.[11] Moreover, patients on maintenance HD with an AV access often encounter events throughout their journey where a CVC may be needed as a bridge between a failed and new AV access. For example, the patency rates for AVGs can be as low as 31.6% at 2 years while a single site analysis showed 34% of patients with AVFs required a second access by 5 years.[23,24] In some situations, CVCs are required as a permanent ("destination") catheter when all viable AV access options have been exhausted.

Among patients treated with PD, approximately 50% will need to transition to another kidney replacement modality before the end of their third year, either due to inadequate clearance or ultrafiltration failure with the loss of residual kidney function and/or repeated bouts of peritonitis.[11] With average transplant wait list times as long as 10 or more years, and many patients being ineligible for kidney transplantation, the current growth and expansion of PD will likely translate to a larger number of patients needing to eventually transition from PD. Modality switch from PD is accompanied by an almost 100% hospitalization rate in the 6 months surrounding it, with an associated cost of approximately $55,000 dollars in the 120 days around each transition event.[25] Nearly all patients who transition from PD to HD do so with a CVC.[23,26]

Table 1. Key Take-Away Points

1. Tunneled CVC will continue to play a vital role in the care of patients with ESKD.
2. Home hemodialysis provides an avenue to improve outcomes and reduce the cost of ESKD care.
3. The ESKD Life-Plan and vascular access recommendations consider tunneled hemodialysis catheters a reasonable approach at times during the patient ESKD journey.
4. Outcomes in patients using CVCs, in-center and at home, are similar.
5. We recommend that the decision to dialyze at home should be independent of the patient's current or long-term vascular access plan.

Abbreviations: CVC, central venous catheter; ESKD, end-stage kidney disease.

THE END-STAGE KIDNEY DISEASE LIFE-PLAN ACCESS NEEDS

A patient's journey with kidney failure and the associated care can be complex and come with events that require an adjustment from long-term decision making to a focus on

"what's next." Incident patients often find their kidney failure diagnosis overwhelming and may resist discussing future decisions such as kidney transplantation and AV access creation. Additionally, some patients decline AV access, placing them at direct odds with their clinicians and dialysis providers, leading to significant dissonance within the care team.[27,28] An initial assessment taking into consideration the patient's age, comorbid conditions, functional status, social support, goals, and preferences can help determine whether in-center HD and referral for AVF creation or AVG placement is the "right" option for the patient at the given time.

Future reassessment should weigh these factors in addition to the patient's anatomy, potential for long-term survival (>1 year), likelihood of successful AV access creation, and transplant eligibility to determine if the Life Plan and vascular access needs should be adjusted. Table 2 summarizes the current KDOQI guidelines regarding access needs, which consider the patient End-Stage Kidney Disease Life-Plan, particularly as it pertains to tunneled CVC.

Many patients are hesitant to have an AV access created due to fear of surgical complications, pain of cannulation, or cosmetic reasons, and some ultimately may choose a permanent CVC.[4] Nephrologists and regulatory bodies should respect a patient's informed choice; importantly, physicians and dialysis providers should not be penalized for respecting a patient's well-informed decision. A study from the SONG-HD initiative showed that the top 3 vascular outcomes of importance and concern were vascular access function, infection, and aneurysms.[29] Patient input into their own care and concern for their health outcomes drives their decision making. Ultimately, the choice of dialysis access should be a shared decision among patients and their care team. Patients should be given the opportunity to make informed decisions based on unbiased information and personal preference.

CLINICAL EXPERIENCE OF CVCS IN HD

Decades of tunneled HD catheter use have yielded substantial data regarding their associated outcomes. While the majority of these data were derived from in-center HD, published data have consistently shown that among patients eligible for AV access, overall complication rates related to infection (local and systemic), thrombosis, and missed or delayed dialysis treatment are consistently higher in patients with CVCs.[30,31] Brown et al[18] studied a cohort of 115,425 incident patients from the USRDS and compared mortality risks in patients with a AVF placed first, a CVC after AVF failure, or a CVC placed first (the referent group). The AVF group had the lowest mortality over 58 months (hazard ratio, 0.50; 95% confidence interval [CI], 0.48-0.52), with mortality rates at 6, 12, and 24 months after initiation of 9%, 17%, and 31%, respectively, compared with 32%, 46%, and 62%, respectively, in the CVC first group.[18] The group with a CVC after failed AVF also experienced lower mortality than the CVC first

Table 2. ESKD Life-Plan and Vascular Access Choice

ESKD Life-Plan and Vascular Access Choice

1.1 KDOQI considers it reasonable that each patient with progressive CKD and/or with an eGFR 15-20 mL/min/1.73 m^2 or already on kidney replacement therapy should have an individualized ESKD Life-Plan that is regularly reviewed, updated, and documented on their medical record. (Expert Opinion)

1.2 KDOQI considers it reasonable to conduct an annual review and update of each patient's individualized ESKD Life-Plan, together with their health care team. (Expert Opinion)

1.3 KDOQI considers it reasonable that, in addition to regular monitoring, a minimum quarterly overall review and update of each patient's vascular access functionality, complication risks, and potential future dialysis access options should be done together with their health care team. (Expert Opinion)

TDC Indications for Use:

2.2 KDOQI considers it reasonable in valid clinical circumstances to use tunneled CVC for short-term or long-term durations for incident patients, as follows (Expert Opinion):

Short-term duration:

- AVF or AVG created but not ready for use and dialysis is required
- Acute transplant rejection or other complications requiring dialysis
- PD patient with complications that require time-limited peritoneal rest or resolution of complication (e.g., pleural leak)
- Patient has a living donor transplant confirmed with an operation date in the near future (eg, <90 days) but requires dialysis
- AVF or AVG complication such as major infiltration injury or cellulitis that results in temporary nonuse until problem is resolved
- Note: In special, limited circumstances where temporary CVC is required to manage a vascular access complication (eg, <2 weeks), it may be acceptable to use a nontunneled CVC

Long-term or indefinite duration:

- Multiple prior failed AV accesses with no available options
- Valid patient preference whereby use of an AV access would severely limit QOL or achievement of life goals and after the patient has been properly informed of patient-specific risks and benefits of other potential and reasonable access options for that patient (if available)
- Limited life expectancy
- Absence of AV access creation options due to a combination of inflow artery and outflow vein problems (eg, severe arterial occlusive disease, noncorrectable central venous outflow occlusion) or in infants/children with prohibitively diminutive vessels
- Special medical circumstances

Abbreviations: AV, arteriovenous; AVF, arteriovenous fistula; AVG, arteriovenous graft; CKD, chronic kidney disease; CVC, central venous catheter; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; KDOQI, Kidney Disease Outcomes Quality Initiative; PD, peritoneal dialysis; QOL, quality of life.

group (hazard ratio, 0.66; 95% CI, 0.64-0.68). The authors suggested that patient factors related to candidacy for AVF creation (rather than the AVF itself), could explain two-thirds or more of the survival benefit observed with an AVF.[18]

Further, CVCs allow for the necessary blood flow rates to effectively deliver adequate HD. Efforts to optimize CVC care (evidence-based imaging for CVC insertion, use of masks, and proper aseptic technique cleansing with chlorhexidine, proper exit site dressings, and other strategies for infection prevention) have reduced catheter infection rates, while newer catheter and cap designs can reduce risk of thrombosis.[32-36] Recent data during the SARS-CoV-2 pandemic suggest that CVC-related infection rates are further reduced with more stringent adherence to infection control procedures.[37]

Patients have used CVCs in HHD to perform their treatments successfully for decades. Over a 12-year period, Lockridge and Kjellstrand reported that 70% of nocturnal HD treatment months were performed using a CVC, with 62 of the 87 patients (71%) dialyzing at home. Cumulative patient survival was reported as 79% and 64% at 5 and 10 years, respectively.[38] Canadian datasets have demonstrated that approximately 30% of patients receiving HHD have done so using CVCs. Overall, the Canadian experience with CVCs has been favorable with respect to all-cause mortality and total adverse event rates.[39] Tennankore et al. reported low adverse event rates for HHD irrespective of vascular access type (0.049 per AVF-year, 0.015 per AVG-year, and 0.022 per CVC-year), with the most common severe adverse event being venous needle dislodgement in patients with AV accesses.[40] Perl et al reported on 11-year data demonstrating that the standard HHD modality (ie, standard thrice weekly vs daily nocturnal), did not meaningfully influence CVC outcomes.[39] Single-center experiences, such as that of Lockridge, demonstrate the ability to achieve good outcomes locally.[41] Review of larger registries, such as the Canadian home dialysis registry, demonstrate the reproducibility of these results over decades.[42] See Table 1 for key take-away points regarding catheter care.

CATHETER USE WITH HHD IS ASSOCIATED WITH SIMILAR RISKS TO CATHETER USE IN-CENTER HD

It is unclear how many patients in the United States are currently dialyzing at home with CVCs. The 2022 USRDS annual report documented that 20% of prevalent patients treated with maintenance HD are using CVCs.[10] Published literature from the Canadian Organ Replacement Registry compared outcomes of AV access to those of CVCs in patients on HHD. Use of an AV access was associated with a hazard ratio for combined death and technique failure of 0.78 (95% CI, 0.64-0.94) and 0.63 (95% CI, 0.43-0.91) for death alone.[42] International and United States data from incident and prevalent patients dialyzing in-center demonstrated a relative risk of death for patients with a CVC to be 1.5 (95% CI, 1.0-2.2) to 1.53 (95% CI, 1.41-1.67), respectively, when compared to patients with AVFs.[11,21,31] While matched cohort data on patients with CVCs on HHD versus in-center HD are not available, the data presented here suggests that the mortality risk associated with CVC use (relative to AV access) at home are similar to those for in-center HD. The similarity in infection and mortality rates can be due to a variety of factors; however, patient activation and CVC training and care are likely central. Patients on home HD tend to be engaged and self-motivated with a high level of activation. In contrast, there is variation in nursing and technician training for CVC care and degree of adherence to infection control measures, and patients in-center tend to have lower activation, which could impact adherence to, and understanding of, appropriate catheter care.[43-45] See Table 3 for instructions on caring for a tunneled CVC at home.

POTENTIAL BENEFITS TO CVC USE AT HOME

In-center thrice weekly HD is dependent on high blood flow rates to achieve small solute adequacy. Tunneled CVCs can have challenges achieving the high flows required by the in-center HD prescription, with data suggesting that approximately 65% of patients on in-center HD with a CVC will have at least one episode of CVC dysfunction (defined as a blood flow <300 mL/min), and this dysfunction was associated with missed treatments, additional access interventions, and hospitalization.[46] The reversal of lines due to inadequate flow further reduces the likelihood of meeting solute clearance targets.[47] Conversely, the flexibility to adjust session length and frequency of HHD allows prescribing to accommodate lower blood flow rates while still achieving "adequacy" targets.[48] For this reason, the KDOQI guidelines changed the definition of CVC dysfunction to recognize the benefits of lower flow rates during longer duration HD.[17]

When appropriately used, a CVC can remove the most time-consuming part of HHD training: self-cannulation of AV access.[49-51] Alleviating the fear and time spent overcoming the psychological burden of learning self-cannulation of AV access, in addition to proper operation of their HD machine could, especially with newer technology, simplify and facilitate training.[5,52] Analysis of USRDS data demonstrates <4% of patients effectuate a transition to home therapy after the initial 90-day experience in-center.[10] Delays in HHD referral awaiting AV access maturation or the patient overcoming the fear of self-cannulation of AV access impede HHD expansion and fosters inertia with in-center HD. Furthermore, patients become susceptible to complications often ameliorated with HHD, especially with a more frequent or nocturnal HD prescription, which allows for slower ultrafiltration, greater hemodynamic stability, and more thorough solute clearance.[53]

Table 3. Caring for a Tunneled CVC at Home

- Ensure the patient has proper training for CVC care.
- Keep the catheter dressing clean and **dry**.
- Make sure the area of the insertion site is clean and the patient changes the dressing once a week or when clinically indicated.
- Keep an emergency dressing kit at home in case you need to change your dressing in between treatments.
- Never remove the cap on the end of your catheter when not receiving treatment. Air **must not** enter the catheter.
- Keep scissors and sharp objects away from your CVC.
- You should only shower using a proper shower protocol taught to you by a health care provider.
- You should not shower until the exit site is completely healed—approximately 6 weeks after insertion.
- Sponge bath until the exit site is fully healed.
- Use proper CVC protection that is commercially available.
- Clear dressing that sticks to your CVC site is inadequate to keep you safe.
- Do not submerge your body in water such as swimming or taking a bath.
- Wear a mask over your nose and mouth anytime the catheter is opened to prevent bacteria from entering the catheter and your bloodstream. Professionals changing the dressing should wear a mask and gloves as well.
- If the area around your catheter feels sore or looks red, call your dialysis care team at once. Ask your dialysis team about signs and symptoms that require immediate attention.
- Know your **Kt/V**[a] and **URR**[b] **(urea reduction ratio)**. Kt/V and URR are numbers that tell you how much dialysis you are getting. The NKF recommends using Kt/V. If you are receiving enough dialysis, your **Kt/V should be at least 1.2. If URR is used, it should be 65% or more**. If your numbers are too low, one possible cause may be that your access is not working well. Ask your dialysis team to check your access.

Abbreviations: CVC, central venous catheter; NKF, National Kidney Foundation.
[a]Kt/V: A number calculated from clinical data to determine the adequacy of a dialysis treatment. Per CMS guidelines the goal Kt/V for a single hemodialysis treatment is 1.2.
[b]URR: An alternative calculation to Kt/V from clinical data to determine the adequacy of a dialysis treatment. The goal URR for a single hemodialysis treatment is 65%.
Source: National Kidney Foundation, https://www.kidney.org/atoz/content/hemocatheter

The expansion of PD is accompanied by an inevitable increase in PD discontinuations and transfers to HD. Because the PD population is already familiar with self-care dialysis, and many are ideal candidates for conversion, when appropriate, PD patients should be transferred to HHD. However, home-to-home transitions (PD to HHD), remain the subject of case reports and small case series.[54] To achieve the Advancing American Kidney Health Initiative goals of home expansion, it is critical to create clearer paths for patients who already manage their care at home to continue to do so when appropriate and when changing modality. In the absence of adequate predictive PD failure models, a home-to-home transition often requires bridging CVC use for HHD. Proper education and referral for HHD irrespective of dialysis access before patients transition from PD can reduce the likelihood of hospitalization and ease the apprehension many patients experience when considering transitioning off PD to HD (whether in-center or HHD).[25] The End-Stage Kidney Disease Life-Plan and referral for vascular access provides specific guidance for this scenario.[17]

Finally, expansion of HHD is dependent on incident patient adoption. As technologies continue to advance and with higher adoption of HD from the intensive care unit to home, urgent start transition to HHD is now a reality. "Transitional care programs" or "dialysis start units" for unplanned or "crash" starts have demonstrated measured success in increasing incident patient home adoption.[55-59] Expansion of such types of units that facilitate the transition from in-hospital acute dialysis start to home dialysis will be challenged by the competition of in-center facilities chairs and the maintenance of critical mass and training of staff required to support such transitional programs. Such programs are successful in the setting of universal health care where financial incentives have less prominence than appropriate patient disposition. Small center experience has demonstrated the ability for patients with unplanned starts to be educated on HHD during their acute stay and transition directly to home training.[60] By leveraging hospital staff to begin the education with newer technology that spans the acute and home environments, urgent start HHD via a CVC is a viable path for patients. Urgent start HHD not only creates a direct path home but alleviates the space and staffing burden associated with in-center HD and vascular access care.

SUMMARY AND RECOMMENDATIONS

With federal initiatives in the United States, quality incentives, and environmental factors at play, the nephrology community must examine current practice and explore opportunities to modify the delivery of care for patients with kidney disease. An AVF remains the optimal access for the majority of patients on HD. Many patients, however, will continue to dialyze through tunneled HD catheters as temporary or more permanent ("destination") options throughout their journey. Published evidence and clinical experience in aggregate suggest that the risks associated with CVC use (relative to AV access) are no higher and perhaps lower at home. Current incentives, federal projects, staffing shortages, and the recent coronavirus pandemic have created an environment where home dialysis expansion is imperative to improve outcomes and reduce costs in an overburdened dialysis care model.

The goal of expansion of HHD must include the newer KDOQI vascular access guidelines movement away from "Fistula First" one-size-fits-all approach and an increased utilization of appropriate vascular access, including tunneled HD catheters for patients on HHD. Recognition

that an appropriate home start, regardless of vascular access type, is an "optimal start" should be reflected in newer payment models. The choice of HD vascular access should be individualized, especially when this may prove pivotal in a patient's decision to preferentially choose HHD. While the nephrology community should continue to encourage preemptive AV access creation in patients with advanced chronic kidney disease who manifest progressive loss of kidney function, current KDOQI vascular access guidelines recognize that a one-size-fits-all fistula approach does not benefit all patients. An individualized plan allows for shared decision making regarding modality and access type and timing—including HHD. Consistent with the end-stage kidney disease (ESKD) Life-Plan, which centers around prioritizing what is best for the patient, patients should choose whether to dialyze at home or in-center first, and then determine the appropriate vascular access needs. The expansion of HHD and the changes needed to meet patient demand, respect patient autonomy, improve outcomes, and reduce cost in kidney care are dependent on it.

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