In the United States, more than 80% of all patients with end-stage renal disease (ESRD) initiate dialysis with hemodialysis, and current reports indicate that this trend has changed little over the past 2 decades.1 Hemodialysis is a life-saving procedure that requires the efficient removal and return of blood to the patient’s body.2 However, despite being a life-sustaining process, hemodialysis is associated with excessive morbidity, mortality, and high societal costs.1,2 The cornerstone of efficient hemodialysis is a well-functioning vascular access that allows for simultaneously efficient blood flow and cannulation. However, finding the optimum vascular access continues to be a challenge for nephrologists, vascular surgeons, and other healthcare providers.3-5 A significant part of the costs and societal impact for patients can be attributed to vascular access dysfunction. By itself, vascular access dysfunction is estimated to exceed $1 billion annually, a large portion of which results from the management of vascular access complications.4 Nevertheless, much of the resources and research in this regard have been invested in

ORIGINAL RESEARCH

Assessing the Level of Patient-Specific Treatment Recommendations in Clinical Practice Guidelines for Hemodialysis Vascular Access in the United States

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BACKGROUND: Hemodialysis is a procedure that requires efficient removal and return of blood to a patient’s body. Despite being a life-sustaining process, hemodialysis is associated with morbidity, mortality, and high societal costs. A significant part of the financial costs to patients and society at large can be attributed to vascular access dysfunction. The cornerstone to efficient hemodialysis is a well-functioning vascular access that simultaneously allows efficient blood flow for dialysis and easy cannulation. It is hypothesized that the poor health outcomes associated with vascular access dysfunction can be improved by paying closer attention to patient-specific factors in clinical guidelines for hemodialysis vascular access. This may require a shift to a more patient-centered approach to vascular access management.

OBJECTIVE: To assess the presence of patient-specific treatment recommendations in the current clinical practice guidelines for hemodialysis vascular access.

METHODS: We conducted a systematic search of PubMed and professional nephrology organization websites for full-text clinical practice guidelines with treatment recommendations regarding hemodialysis vascular access. We developed a coding sheet to document the number of patient-specific treatment recommendations and other quality attributes found in the extracted clinical practice guidelines.

RESULTS: Our search resulted in the extraction of 5 clinical practice guidelines for final review. Only 1 of the 5 extracted guidelines was found to contain patient-specific treatment recommendations, but the treatment recommendations were limited to juvenile patients. Of the 5 clinical practice guidelines, 4 were published within the past decade (ie, after 2006).

CONCLUSION: Our findings show that current clinical practice guidelines for hemodialysis vascular access lack patient-specific recommendations. Future clinical guidelines must consider patient-specific treatment recommendations with the goal of improving hemodialysis vascular access outcomes for patients, a goal that is supported in the recommendations of the National Kidney Foundation.

KEY WORDS: clinical practice guidelines, dialysis, end-stage renal disease, hemodialysis, patient-specific treatment recommendations, vascular access

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KEY POINTS

- Optimum vascular access can be difficult to achieve in patients undergoing hemodialysis, which can result in high costs, morbidity, and mortality.
- The cornerstone to efficient hemodialysis is a well-functioning vascular access that facilitates efficient blood flow for dialysis and for easy cannulation simultaneously.
- This study assessed patient-specific treatment recommendations in current clinical practice guidelines for hemodialysis vascular access.
- Of the 5 clinical practice guidelines reviewed, only 1 contained patient-specific treatment recommendations.
- The 5 guidelines agree that arteriovenous fistulae is the first choice of access, followed by arteriovenous grafts, and advocate against central venous catheter use for long-term dialysis.
- Current clinical practice guidelines for hemodialysis vascular access lack patient-specific treatment recommendations.
- Future guidelines should include patient-specific treatment recommendations to improve vascular access outcomes for patients.

The development and management of vascular access technologies for hemodialysis. In recent decades, clinical practice guideline developers have devoted much attention to vascular access design and implementation in an effort to improve dialysis outcomes. Despite these efforts, vascular access outcomes continue to be suboptimal.

In the United States, 4 types of vascular access are available for hemodialysis, including tunneled central venous catheters, arteriovenous grafts, arteriovenous fistulae, and most recently, the hemodialysis reliable outflow graft, which has been growing in popularity.

Vascular access creation has become a common surgical operation in the United States, with more than 500,000 procedures performed during the past decade. Vascular access creation is such a critical aspect of hemodialysis that for the first time in its history, the United States Renal Data System, one of the major entities for publishing ESRD data and information, dedicated an entire chapter to this important topic in its 2016 annual report.

Much of the debate within the nephrology community surrounding hemodialysis vascular access focuses on the ostensible inability of healthcare systems to achieve the optimum vascular access for the right patient. It has been largely agreed that the use of tunneled central venous catheters should be discontinued, because prolonged use of these catheters can result in bloodstream infections, mechanical injury, and patient discomfort, which can lead to costly hospitalizations. However, fistulae and grafts can also have their own inherent problems, including high failure rates that result in loss of primary assisted patency.

Despite being designated as the preferred type of access for hemodialysis as a consequence of its lower risk for malfunction and infection compared with other vascular access technologies, the arteriovenous fistula is limited by long maturity times and high failure rates. Furthermore, the arterial and venous systems of many patients make them poor candidates for a fistula.

When patients are deemed unsuitable for a fistula, a graft is the second best choice. However, grafts are prone to frequent stenosis and thrombosis, and their long-term primary and assisted primary patency are not as good as with fistulae. Furthermore, compared with fistulae, grafts are associated with a higher rate of postsurgery complications that can significantly affect mortality, morbidity, and treatment costs. Therefore, despite being a fundamental aspect of hemodialysis therapy, the provision of quality vascular access for hemodialysis remains difficult to achieve.

The major barrier to successful dialysis therapy has always been, and continues to be, the inability to establish a reliable vascular access management program that can optimize cost and clinical outcomes simultaneously. This has caused many experts in the ESRD community to shift their focus toward a more patient-specific approach to vascular access management, which challenges the quality of existing treatment recommendations for hemodialysis. Many experts also believe that the current treatment recommendations for hemodialysis vascular access do not sufficiently address patient perspectives, nor do they consider patient-specific characteristics, such as age, arterial and venous anatomy, body mass index, race, sex, life expectancy, comorbid conditions, and functional status at the initiation of dialysis.

In an effort to improve arteriovenous fistulae patency rates, the 2006 edition of the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative provided recommendations for vessel mapping, as well as access management in pediatric patients. Today, the fastest growing segment of the US population with ESRD involves people aged ≥65 years, many of whom have deteriorated arterial and venous anatomies. This raises moral, ethical, financial, social, legal, and quality-of-life concerns with respect to how vascular access is made available to this particular segment of the population of people undergoing dialysis.

It is important for nephrologists, vascular surgeons,
registered nurses, and other clinicians who provide day-to-day care for dialysis patients to have a thorough understanding of patients’ needs and the relative appropriateness of vascular access devices for specific conditions; however, this type of information is not easily attainable.

Therefore, the objective of this study was to assist in bridging this gap by reviewing the available clinical practice guidelines for hemodialysis vascular access to document how patient-specific treatment recommendations were addressed during the guideline development process. This information can help future guideline developers to determine the feasibility of incorporating patient-specific treatment recommendations into their practice guidelines.

Clinical Practice Guidelines

The Institute of Medicine defines clinical practice guidelines as “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.” Clinical practice guidelines are usually found in published materials that summarize the directions or the principles to assist healthcare providers with patient-care decisions regarding the appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances.

Clinical practice guidelines are usually developed by government agencies, healthcare institutions, professional societies, governing boards, or expert panels. They are designed for assessing and evaluating the quality and effectiveness of healthcare delivery in terms of measuring improved health, reducing variation in services or procedures performed, and reducing variation in health outcomes. The guidelines are subject to continuous revision, as is warranted by the evolution of medical knowledge, technology, and practice.

In healthcare management, clinical performance targets are designed to improve patient outcomes through quality improvement, but evidence linking target attainment and patient outcomes in clinical practice is often lacking. It is generally agreed within the healthcare community that clinical practice guidelines can improve the quality of healthcare by recommending evidence-based best practices for managing medical conditions. This can be achieved by systematically reviewing the evidence and through collaborative efforts that involve the perspectives of clinicians and patients. However, in most cases, the perspective of patients is missing from clinical practice guideline recommendations. It is important to note that the quality of care for patients undergoing hemodialysis is only as good as the guidelines developed to manage their health condition.

Evidence-based clinical practice guidelines can assist providers and patients in making decisions about appropriate healthcare for specific clinical conditions, as well as play an important role in the development of health policy. For example, those evidence-based clinical practice guidelines that were developed for vascular access management can optimize patient outcomes and use of healthcare resources. Modern-day clinical practice guidelines have evolved to cover a wide variety of topics in healthcare. However, their potential benefits are limited by their inherent quality, especially if appropriate methodologies and rigorous strategies are not applied during the guideline development process.

Because clinical practice guidelines are critical for helping providers and patients make optimal choices among competing healthcare interventions, such guidelines should aim at formulating explicit and specific recommendations that can be adopted in clinical practice, produce better clinical outcomes, including better quality of life for patients, and promote cost-effectiveness.

Several practice guidelines have been developed to improve vascular access outcomes and overall quality of life for patients undergoing dialysis. These guidelines were designed to provide guidance regarding the placement and management of vascular access devices, and for reducing infectious, mechanical, thrombotic, and other adverse events associated with the selection, placement, and maintenance of vascular access devices.

There is considerable potential for including patient-specific treatment recommendations in future clinical practice guidelines for hemodialysis vascular access. A revised version of the Canadian Society of Nephrology’s guidelines for managing chronic kidney disease includes patient-specific clinical recommendations for diabetes, hypertension, dyslipidemia, and anemia, and even lifestyle management. Similar guidelines are also available in Australia, the United Kingdom, and the United States; however, it is not clear whether any of the patients for whom the guidelines were developed were receiving hemodialysis.

Methods

We systematically searched PubMed for full-text clinical practice guidelines published in peer-reviewed journals in the English language. We also searched websites of professional societies and healthcare organizations that specialize in dialysis care to find relevant clinical practice guidelines for evaluation. The search strings included “hemodialysis vascular access,” “clinical practice guidelines,” “clinical practice guidelines for hemodialysis vascular access,” and “patient-specific clinical practice guideline recommendations.” The search was limited to free full-text guidelines with recommendations for hemodialysis vascular access. Further eligibility criteria required the guidelines to be published between the years 2000 and 2016, be developed by a professional society or...
The initial search strings returned 73 items, including 64 from PubMed and 9 from websites of professional societies or government organizations. After further screening, only 5 clinical practice guidelines met the study criteria used in this study. An outline of the screening process and the reasons for exclusion of noneligible clinical practice guidelines are provided in the Figure.

The characteristics of the extracted clinical practice guidelines are outlined in the Table. Of the 5 clinical practice guidelines eligible for inclusion in this evaluation, only 2 included treatment recommendations for 3 (ie, arteriovenous fistulae, arteriovenous grafts, and central venous catheters) of the 4 vascular access options noted earlier.

The other 3 clinical practice guidelines provided treatment recommendations only for central venous catheters. None of the 5 clinical practice guidelines provided treatment recommendations for the hemodialysis reliable outflow graft; however, considering the recent time frame (ie, 2008) during which the hemodialysis reliable outflow graft was endorsed by the US Food and Drug Administration as a reliable vascular access alternative, this finding is not surprising.

The 5 selected studies were characterized by considerable variation in their time of publication and by the number of treatment recommendation categories. Of the 5 eligible clinical practice guidelines, 4 were published after 2007. The number of treatment recommendations ranged from 4 to 13 (Table). For convenience and space considerations, only a summary of the treatment recommendations in each clinical practice guideline is provided in the Table.

The 2 clinical practice guidelines that address at least 3 vascular access alternatives include a treatment category for access selection. Although not shown in the Table, these clinical practice guidelines were unanimous in their promotion of arteriovenous fistulae as the access of first choice, followed by arteriovenous grafts. These 2 clinical practice guidelines were also unanimous in their nonadvocacy of central venous catheters for long-term dialysis.

Only 1 clinical practice guideline included patient-specific recommendations. However, these recommendations were limited to juvenile patients and made no provisions for other age categories. It must be noted that this same guideline supports vessel mapping, which can assist with the accurate placement of vascular accesses, in its recommendations for future research.

No other evidence of patient-specific treatment recommendations specifically for vascular access was identified in the clinical practice guidelines.

Discussion

During the study’s coding process, patient-specific treatment recommendations were identified for other aspects of hemodialysis therapy; however, because the study objective was to identify patient-specific treatment recommendations explicitly for vascular access, those treatment guidelines are outlined in the Figure.
This review evaluated the level of patient-specific treatment recommendations in clinical practice guidelines for hemodialysis vascular access. This study revealed that clinical practice guidelines for hemodialysis vascular access lack patient-specific treatment recommendations.

However, patient-specific treatment recommendations for other aspects of hemodialysis therapy were unveiled during our study. This is an encouraging discovery, because there is great need for the inclusion of patient-specific treatment recommendations in future clinical practice guidelines for hemodialysis vascular access in the United States. At the very least, this assertion is supported by the National Kidney Foundation, whose treatment recommendations for hemodialysis vascular access are among the most widely used for dialysis therapy globally. Their clinical practice guidelines were among the 5 guidelines included in our study.

Limitations

This study sought to determine the level of patient-specific treatment recommendations in clinical practice guidelines for hemodialysis vascular access in the United States. Therefore, the study findings cannot be applied to all clinical practices.

Table Characteristics of Clinical Practice Guidelines for Hemodialysis Vascular Access

<table>
<thead>
<tr>
<th>Society/year of publication or update</th>
<th>Access type(s) addressed</th>
<th>Patient-specific recommendations?</th>
<th>Summary of guideline recommendations</th>
</tr>
</thead>
</table>

*Currently, the National Kidney Foundation’s patient-specific treatment recommendations for vascular access are limited to juveniles. However, the National Kidney Foundation supports research that includes patient-specific treatment recommendations with respect to age, sex, comorbid conditions, and selection and placement of accesses in future guidelines.

The National Kidney Foundation’s research recommendations are grouped into 3 categories: critical research, important research, and research of interest. Each category has guideline recommendations for future research. At the time of this study, none of the research recommendations targeted vascular access. However, because of high rates of cardiovascular mortality and morbidity among young patients with heart disease, a critical research recommendation is for studies on inflammation, cardiovascular fitness, nutrition assessment, malnutrition treatment, and health-related quality of life of pediatric patients with heart disease.
be generalized to clinical practice guidelines developed by foreign healthcare organizations.

Furthermore, the emphasis was strictly on identifying patient-specific treatment recommendations for hemodialysis vascular access, hence patient-specific treatment recommendations for other aspects of dialysis therapy were not considered.

Finally, by focusing on the primary study objective, we did not critically appraise the overall quality of the included guidelines as purported by developers of guideline appraisal tools.22

Conclusion
It is difficult to find vascular access technologies that simultaneously improve clinical outcomes (including the patient’s health-related quality of life) and reduce treatment costs for patients undergoing hemodialysis. This has caused many experts in the nephrology community to question the quality of existing clinical practice guideline recommendations for hemodialysis vascular access. It is generally accepted among dialysis experts that greater attention should be given to patient-specific factors when developing clinical practice guideline recommendations. Considering the amount of discussion provided here regarding the quality of clinical practice guidelines and patient-centered approaches to healthcare, we hope that this study can be a catalyst for continued improvements in these important aspects of care for patients undergoing hemodialysis.

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Author Disclosure Statement
Dr Queeley, Dr Campbell, and Dr Ali have no conflicts of interest to report.

References
The Challenge of Maintaining Vascular Access in Patients with End-Stage Renal Disease

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Willem J. Kolff, MD, PhD, is considered the father of dialysis. This young Dutch physician developed the first artificial kidney in 1943. He began his research after watching a patient die slowly from kidney failure. Determined to find a solution, he found a publication from Johns Hopkins University, where the renowned pharmacologist John J. Abel, MD, was studying the removal of toxins from the blood of animals. After World War II, Dr Kolff came to the United States to continue his studies, despite receiving a considerable amount of vitriol from colleagues who did not believe that a machine would be a long-term solution for end-stage renal disease (ESRD). Dr Kolff was not dissuaded by criticism and developed the basic design for modern-day hemodialysis, paving the way for the first kidney transplant in 1954.

Decades later, the largest challenge facing hemodialysis remains how to maintain vascular access over the long-term. In 1960, Belding H. Scribner, MD, of the University of Washington, developed the concept of a shunt, using a plastic tube inserted into an artery and another into a vein. After the dialysis treatment was completed, the tubes were connected outside the body using a U-shaped device that would result in a shunt from the artery to the vein. This allowed patients to have dialysis without needing an invasive procedure for each dialysis treatment. In 1962, Dr Scribner started the world’s first outpatient dialysis facility. Since then, there have been many advances in vascular surgery, such as arteriovenous fistula creation, prosthetic dialysis grafts, tunneled catheters, and techniques for peritoneal dialysis.

PATIENTS: The National Kidney Foundation (NKF), which advocates for patients with kidney disease and their families, was officially named in 1964. In the years that followed, the NKF was instrumental in securing the first federal funds for kidney programs. This led to the 1972 milestone of the passage of legislation that provided financing from the federal government for nearly all Americans with kidney failure. Controversial as that entitlement remains today, it was, and remains, the only categorical coverage for any disease in the United States.

The NKF is also responsible for developing the first clinical practice guidelines in nephrology, which are now known as the Kidney Disease Outcomes Quality Initiative. The NKF supports global research and established the Kidney Disease: Improving Global Outcomes clinical practice guidelines. Establishing standards in chronic kidney disease (CKD) presents a challenge, because CKD represents a spectrum of disease with patient-specific complications at every disease stage.

Queeley and colleagues provide a nice review of the complexity of patient-specific factors that limit the development of practice guidelines for patients who require hemodialysis vascular access. The need for future guidelines to include patient-specific treatment recommendations is obvious and achievable. Many such guidelines already exist for the spectrum of CKD, such as hypertension, diabetes, stroke, and cardiovascular disease (CVD). According to its website, the NKF is currently “using the contributions of leading investigators from 45 studies… [and] is creating and analyzing the world’s largest dataset about patient outcomes at all stages of chronic kidney disease.” This research supports Queeley and colleagues’ conclusion that patient-specific guidelines for hemodialysis vascular access will optimize care in these complex and chronically ill hemodialysis patients.

The prevalence of renal disease is increasing in the United States, and, according to the NKF, 1 in 3 Americans are at risk for kidney disease because of the growing number of patients with risk factors for CKD, including high blood pressure, diabetes, and CVD. The obesity epidemic in US children will likely lead further toward an alarming number of young adults with renal disease. Untreated and untreated patients are at risk for requiring hemodialysis at some point.

In addition to behavioral and lifestyle changes, education is paramount. The average young adult in the United States is often unaware of the perils and morbidity of hemodialysis. Although renal transplantation is one of the great achievements of modern medicine, donor organ availability remains a major limiting factor. Therefore, most patients will require long-term hemodialysis, which, in turn, will require long-term, safe vascular access.
A challenge for patients is that their renal care may be managed by many clinicians, including a primary care physician, cardiologist, vascular surgeon, and/or nephrologist. Because most of the factors leading to CKD are chronic diseases, such as hypertension and diabetes, patients may not have their care managed according to NKF guidelines until they have later-stage disease. The educational reach of patient-specific guidelines needs to include family physicians, internists, cardiologists, and nephrologists to ensure that the standard of care is maintained across specialties. An educated patient is the best prevention tool. The NKF does an excellent job providing resources for patients, who, in turn, need to use these resources and contribute to the success of their care.

**PROVIDERS:** Whenever multiple disciplines are involved in disease management, the opportunity exists for collaboration, as well as dysfunction. The decision to proceed with dialysis and the choice of the type of dialysis are typically made by the nephrologist. The range of dialysis choices and the types of vascular access vary.

Specific to vascular access, a tunneled catheter is typically placed by an interventional radiologist, whereas an arteriovenous fistulae or graft is placed by a vascular surgeon. However, the management of a fistulae and graft may now likely be managed by a relatively new field, known as interventional nephrology. Across the United States there are vascular access centers where interventional nephrologists manage vascular access issues, including complications such as arteriovenous fistula stenosis or the declotting of vascular access grafts. This may cause conflict with vascular surgeons, who may not agree with the management of fistula and grafts that they had placed, only to receive such patients later, often after hours, for emergency revisions.

Just as patients with chronic renal failure may have multiple providers caring for various aspects of their disease, providers are now faced with overlap, and possibly even competition. Despite the growing number of interventional internists in many fields, to ensure that best practices are met, providers must find a way to work together, share patient-specific guidelines, and develop guidelines jointly from the start. Most of all, providers from all fields should be transparent and share their outcomes. Only through shared-outcomes research can we hope to improve patient care.

**PAYERS:** When Medicare was first established in 1965, it did not provide coverage for dialysis. As noted earlier, once the dialysis technology improved, a lack of insurance coverage became a barrier to treatment. In 1972, Congress passed the Medicare law that extended coverage to individuals aged <65 years with chronic ESRD. And the ESRD amendment of 1978 encouraged home dialysis and provided reimbursement for renal transplantation. The ESRD provisions of the Omnibus Budget Reconciliation Act of 1981 called for the establishment of a prospective payment system for outpatient dialysis with a single rate to cover all supplies and services.

Since 2003, many improvements have been made in Medicare’s payment models, including bundled payments, improving billable dialysis-related drugs and biologics, case-mix adjustments, and outcomes reporting. More than 650,000 patients have ESRD annually in the United States, and this number is increasing by 5% annually. In addition, >100,000 American patients are on the kidney transplant list annually, but <20,000 donor kidneys are available for them, and the need for donor kidneys is rising by 8% annually.

The cost of dialysis in the United States is staggering. Although patients with ESRD make up only 1% of the Medicare population, their healthcare costs account for 7% of the Medicare budget. According to Medicare, hemodialysis costs an average of $89,000 per patient annually. This amounts to an annual hemodialysis cost of $42 billion in the United States, of which $34 billion is covered by Medicare. The remaining cost is paid by Medicaid or private insurance, or out of pocket by patients.

Research is ongoing regarding a bioartificial kidney. This could drastically reduce the cost of care for patients with ESRD and save many lives. Until then, patient-specific guidelines must continue to be developed, along with collaboration among all disciplines, to ensure best practices. Payers should insist on these efforts and should provide reimbursement based on compliance, quality, and cost transparency.

5. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; Bethesda, MD.