Illuminating the Decision-Making Process among Patients with Advanced CKD Opting to Forgo Dialysis

For patients with advanced chronic kidney disease (CKD), maintenance dialysis offers life-saving benefits that can include restoration of health and improved quality of life. However, the potential benefits of dialysis in extending life and managing the signs and symptoms of uremia are outweighed by the harms that may be associated with maintenance dialysis for some patients, including substantial treatment burden and the risk of progressive loss of physical, social, and cognitive function.

Current data on decision making regarding dialysis in the United States are largely limited to patients who are receiving maintenance therapy; results of studies reveal that dialysis is often presented to patients as a necessity rather than a treatment choice. Data from the US Veterans Affairs (VA) healthcare system suggest that only 14.5% of patients with advanced CKD (or those making decisions on their behalf) opt not to pursue dialysis. Other data indicate that the proportion of patients forgoing dialysis may be even less common in other US healthcare settings.

Susan P. Y. Wong, MD, MS, and colleagues recently conducted an in-depth qualitative analysis to gain a deeper understanding of how decisions not to pursue dialysis occur.

Real-World Long-Term Effectiveness of Sucroferric Oxyhydroxide in Managing Hyperphosphatemia

Patients with advanced chronic kidney disease (CKD) and end-stage renal disease (ESRD) often experience hyperphosphatemia. Due primarily to the progressive inability of the kidneys to appropriately excrete phosphorus, disrupted phosphorus homeostasis leads to phosphorus accumulation. There have been few data available on whether the modality used for renal replacement therapy poses a risk factor for AF among dialysis patients. The researchers conducted a retrospective analysis found a favorable rate of live births in this patient population; however, the risks, both maternal and fetal, are high.

Dialysis Modality and Rates of Incident Atrial Fibrillation in Older Adults

Atrial fibrillation (AF), the most common sustained arrhythmia in the general population, is particularly common among patients with end-stage renal disease (ESRD). The prevalence of AF is as high as 10% among patients in the United States on hemodialysis. There is a steep increase in the percentage with age, reaching as high as 25% of patients ≥85 years of age. Among older patients, the cumulative incidence of newly diagnosed AF during the first year of dialysis therapy is nearly 15%.

AF is associated with poor health outcomes that include higher mortality rates, excess rates of ischemic stroke, systemic thromboembolism, myocardial infarction, heart failure, and kidney disease. Patients with ESRD and AF also incur increased healthcare costs.

There are several risk factors for the development of AF including sociodemographic characteristics (older age, female sex, white race, and non-Hispanic ethnicity), and chronic conditions such as heart failure, diabetes, and hypertension; these factors increase the risk of AF in the population of patients with kidney failure receiving maintenance dialysis.

According to Jingbo Niu, MD, DSc, and colleagues, there are few data available on whether the modality used for renal replacement therapy poses a risk factor for AF among dialysis patients. The researchers conducted a retrospective analysis.
INDICATION
Velphoro® (sucroferric oxyhydroxide) is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

IMPORTANT SAFETY INFORMATION
• Velphoro chewable tablets must be administered with meals. Do not swallow whole.
• Patients with peritonitis during peritoneal dialysis, significant gastric or hepatic disorders, following major gastrointestinal (GI) surgery, or with a history of hemochromatosis or other diseases with iron accumulation have not been included in clinical studies with Velphoro. Monitor effect and iron homeostasis in such patients.
• In a parallel design, fixed-dose study of 6 weeks duration, the most common adverse drug reactions to Velphoro chewable tablets in hemodialysis patients included discolored feces (12%) and diarrhea (8%).

KDIGO – Kidney Disease: Improving Global Outcomes.

Updated KDIGO guidelines recommend limiting the use of calcium-based binders...

SWITCHING TO VELPHORO
CAN MAKE A WORLD OF DIFFERENCE

Double the percentage of patients achieved phosphorus goal with half the pill burden*1

Visit RealWorldVelphoro.com TO SEE THE DIFFERENCE A SWITCH CAN MAKE

* A retrospective analysis of pharmacy data assessed the real-world effectiveness of Velphoro in 1,029 adult in-center hemodialysis patients who were switched to Velphoro during routine care. The study compared the proportion of patients with phosphorus levels ≤ 5.5 mg/dL and the mean prescribed phosphate binder pills/day at baseline (3 months prior to Velphoro; binders included sevelamer carbonate, calcium acetate, and lanthanum carbonate) and during Velphoro follow-up (6 months after switch to Velphoro, n=424). This was a noninterventional analysis and did not impact prescriptions or prescribing patterns.

INDICATIONS AND USAGE
Velphoro (sucroferric oxyhydroxide) is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

DOSE AND ADMINISTRATION
Velphoro tablets must be chewed and not swallowed whole. To aid with chewing and swallowing, tablets may be crushed.

The recommended starting dose of Velphoro is 3 tablets (1,500 mg) per day, administered as 1 tablet (500 mg) 3 times daily with meals.

Adjust by 1 tablet per day as needed until an acceptable serum phosphorus level is reached, with regular monitoring afterwards. Titrate as often as weekly.

DOSE FORMS AND STRENGTHS
Velphoro (sucroferric oxyhydroxide) chewable tablet 500 mg.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
Patients with peritonitis during peritoneal dialysis, significant gastric or hepatic disorders, following major gastrointestinal surgery, or with a history of hemorrhachromatosis or other diseases with iron accumulation have not been included in clinical studies with Velphoro. Monitor effect and iron homeostasis in such patients.

ADVERSE REACTIONS
In a parallel design, fixed-dose study of 6 weeks duration, the most common adverse drug reactions to Velphoro chewable tablets in hemodialysis patients included discolored feces (12%) and diarrhea (6%).

The following adverse reactions were identified during post approval use of Velphoro and were reported voluntarily from a population of uncertain size.

Gastrointestinal Disorders: tooth discoloration
Skin and Subcutaneous Tissue Disorder: rash

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Medical Care North America at 1-800-323-5188 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
Velphoro can be administered concomitantly with oral calcitriol, ciprofloxacin, digoxin, enalapril, furosemide, HMG-CoA reductase inhibitors, hydrochlorothiazide, losartan, metoprolol, nifedipine, omeprazole, quinidine and warfarin.

Take acetylsalicylic acid, cephalexin and doxycycline at least 1 hour before Velphoro.

Take levothyroxine at least 4 hours before Velphoro.

For oral medications not listed above where a reduction of bioavailability would be clinically significant consider separation of the timing of administration. Consider monitoring clinical responses or blood levels of the concomitant medication.

USE IN SPECIFIC POPULATIONS
Pregnancy

Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at doses up to 16 and 4 times, respectively, the human maximum recommended clinical dose on a body weight basis, and have not revealed evidence of impaired fertility or harm to the fetus due to Velphoro. However, Velphoro at a dose up to 16 times the maximum clinical dose was associated with an increase in post-implantation loss in pregnant rats. Animal reproduction studies are not always predictive of human response. There are no adequate and well-controlled studies in pregnant women.

Labor and Delivery

No Velphoro treatment-related effects on labor and delivery were seen in animal studies with doses up to 16 times the maximum recommended clinical dose on a body weight basis. The effects of Velphoro on labor and delivery in humans are not known.

Nursing Mothers

Since the absorption of iron from Velphoro is minimal, excretion of Velphoro in breast milk is unlikely.

Pediatric Use

The safety and efficacy of Velphoro have not been established in pediatric patients.

Geriatric Use

Of the total number of subjects in two active-controlled clinical studies of Velphoro (N=835), 29.7% (n=248) were 65 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

OVERDOSAGE

There are no reports of overdosage with Velphoro in patients. Since the absorption of iron from Velphoro is low, the risk of systemic iron toxicity is low. Hypophosphatemia should be treated by standard clinical practice.

Velphoro has been studied in doses up to 3,000 mg per day.

HOW SUPPLIED/STORAGE AND HANDLING

Velphoro are chewable tablets supplied as brown, circular, bi-planar tablets, embossed with “PA 500” on 1 side. Each tablet of Velphoro contains 500 mg iron as sucroferric oxyhydroxide. Velphoro tablets are packaged as follows:

NDC 49230-645-51 Bottle of 90 chewable tablets

Storage

Keep the bottle tightly closed in order to protect from moisture.

Store at 25°C (77°F) with excursions permitted to 15 to 30°C (59 to 86°F).

PATIENT COUNSELING INFORMATION

Inform patients that Velphoro tablets should be chewed or crushed. Do not swallow whole (see Dosage and Administration). Velphoro should be taken with meals.

Instruct patients on concomitant medications that should be dosed apart from Velphoro (see Drug Interactions).

Inform patients that Velphoro can cause discolored (black) stool, but this discoloration of the stool is considered normal with oral medications containing iron.

Inform patients that Velphoro can stain teeth.

Inform patients to report any rash to their healthcare professional.

Distributed by:
Fresenius Medical Care North America
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Waltham, MA 02451
Personalized Approaches to the Diagnosis and Treatment of Chronic Kidney Disease

Recent publications using whole exome sequencing (WES) in chronic kidney disease (CKD) patients place nephrology squarely in the cusp of a major advance in the diagnosis and treatment of CKD1-4. Patients with any form of CKD could benefit, but especially those with a strong family history of CKD with no obvious cause.

WES will become a central part of our work-up of patients, as it is currently for patients with cancer. Moreover, as WES becomes a mainstay in the work-up of patients with CKD we will all need to know more about WES: who should be tested and what should we do with the information?

WES has its origins with traditional genetic sequencing (the Sanger method, named for Frederick Sanger), using gels that were expensive, laborious to work with, and inefficient. Automation speeded up sequencing, but it still required years to sequence a person's whole genome. Because only 1% of the genome comprises the protein-coding sequences (the exons), it soon became clear that using next generation sequencing such as WES to sequence all of the exons (collectively known as the exome), most variations in the protein coding regions could be detected. WES both increased efficiency and reduced cost. However, a key disadvantage of sequencing the whole exome rather than the whole genome is that valuable information that might reside in non-coding sequences (introns) could be lost. Still, for clinical diagnostic purposes rather than research efficiency, cost and speed has won over comprehensiveness.

A recent potentially landmark paper published in the New England Journal of Medicine by Groopman and colleagues from Columbia University1 is really well done and represents a huge advance in research efficiency, cost and speed has won over comprehensiveness. The study supported three important conclusions:

1. In many patients, particularly from the better-characterized CUMC cohort, genetic diagnosis using WES provided new clinical insight, including more precise diagnosis, the potential for better estimation of the risk of nephropathy progression, and guidance for donor selection for transplantation.

2. WES enabled identification of a specific underlying cause among those with CKD—by pinpointing the precise genetic subtype of focal segmental glomerulosclerosis or cystic disease, for example—allowing for either better classification or even reclassification of disease.

3. WES helped distinguish patients with CKD from genetic causes that result in structural changes to the glomerular barrier versus from causes that might have acquired immunological etiology, the latter potentially being more amenable to targeted immunosuppression—sparing some patients the unnecessary risk of toxicity from powerful immunosuppressive medications that might not work.

The take home message is that personalized approaches in CKD diagnosis and management are now at our doorstep and we had better take notice.

REFERENCES
associations between high levels of serum phosphorus and increased risk of cardiovascular morbidity and mortality. In a previous large national study, the risk of mortality among patients with CKD receiving hemodialysis therapy increased by 6% for each 1 mg/dL increase in serum phosphate level above the Kidney Disease Outcomes Quality Initiative target of 3.5 to 5.5 mg/dL.

Oral phosphate binders are effective in lowering serum phosphorus. However, those agents have high pill burdens and low adherence rates. There is an association between reduced adherence to prescribed phosphate binder therapy and increased concentrations of serum phosphorus.

Sucroferic oxyhydroxide (SO; Velphoro® [Fresenius Medical Care Renal Therapies Group, Waltham, MA]) is a noncalcium, chewable, iron-based phosphate binder indicated for treating hyperphosphatemia in patients on dialysis therapy. Previous studies have shown similar efficacy, good tolerability, and lower pill burden when compared with sevelamer carbonate.

Results of a recent 6-month retrospective analysis of pharmacy data of patients on hemodialysis prescribed SO as part of routine care showed a >50% decrease in pill burden and a 95% increase in the proportion of patients with serum phosphorus levels <5.5 mg/dL. Jessica Kendrick, MD, MPH, and colleagues conducted historical cohort analyses of de-identified electronic medical records to examine the real-world effectiveness of SO in the management of serum phosphorus levels over a 1-year period in patients receiving hemodialysis. Results were reported online in the Journal of Renal Nutrition [doi.org/10.1053/j.jrn.2018.11.002].

The analysis included comparisons between the 91-day period prior to SO initiation (baseline) and four consecutive 91-day intervals of SO treatment (Q1-Q4). Clinical measures included achievement of target phosphorus levels (≤5.5 mg/dL) and the mean number of phosphate binder pills per day. The analysis included adult (age >18 years) in-center hemodialysis patients from Fresenius Kidney Care units who switched from another phosphate binder to SO therapy as part of routine care between March 2014 and March 2015.

There were 3110 patients who met the criteria during the analysis period. Of those, 2580 were excluded due to changing dialysis facilities (n=201), non-continuous SO prescription days (n=785), prescription of combination phosphate binder therapy with SO (n=1024), or switching to a new phosphate binder (n=570).

Of the 530 adults in the analytic cohort, 41.0% (n=217) were black/African American and 16.4% (n=87) were Hispanic/Latino. All patients received hemodialysis three times per week. During baseline, the patients were prescribed monotherapy with sevelamer (59.8%), calcium acetate (27.6%), lanthanum carbonate (7.9%), or magnesium carbonate (0.4%) or were switched among those agents over the 3-month period.

In the month prior to the switch to SO, 18.7% of patients had in-range serum phosphorus concentrations (≤5.5 mg/dL). During the period of SO therapy, as many as 39.8% met that criterion, for a 113% increase in patients achieving target serum phosphorus goals. In the month prior to SO therapy, mean pill burden was 8.7 pills per day. Relative to that month, there was an association between SO therapy and at least a 49% reduction in mean pill burden during each subsequent month. Over the year of SO therapy, the mean SO pill burden was uptitrated from 4.0 at months 1 and 2 to 4.4 at month 12.

At baseline, the mean serum phosphorus concentration was 6.83 and only 17.7% of the patients in the analysis cohort had attained a serum phosphorus level of ≤5.5 mg/dL on their phosphate binder. Following the switch to SO, at each follow-up quarter, there was an improvement in mean serum phosphorus level from baseline: 6.54 mg/dL at Q1, 6.37 mg/dL at Q2, 6.25 mg/dL at Q3, and 6.19 mg/dL at Q4 (P<0.001 vs baseline).

The proportion of patients who achieved target serum phosphorus levels was higher than baseline throughout the SO treatment period: 24.5% at Q1, 30.5% at Q2, 36.4% at Q3, and 36.0% at Q4 (P<0.001 for each quarter vs baseline). In further analyses, the proportions of patients reaching serum phosphorus concentrations ≤4.5 mg/dL increased from 4.7% at baseline to 6.6% at Q1, 11.6% at Q2, 12.1% at Q3, and 13.7% at Q4 (P<0.001 for each interval vs baseline).

When analyzed by prespecified subgroups of interest (black/African American patients, Hispanic/Latino patients, women), findings regarding the effectiveness of SO were similar.

The researchers cited some limitations to the study, including the retrospective design and lack of a comparator group followed up during the same study period, the reasons for switching from baseline phosphate binder to SO not being available, not accounting for specific nutritional education or advice given to patients, and lack of data on the use of protein supplements.

“In conclusion, results from this study demonstrate that completion of 1 year of treatment with SO was effective in controlling hyperphosphatemia in patients on hemodialysis with fewer prescribed pills per day than other PBs,” the researchers said. Funding for the analysis was provided by Fresenius Medical Care Renal Therapies Group.

TAKEAWAY POINTS

- Researchers conducted historical cohort analyses to examine the real-world effectiveness of sucroferic oxyhydroxide (SO), a phosphate binder with a low pill burden, in managing serum phosphorus in patients prescribed SO as part of routine care.
- Over a 1-year period, among SO patients in the analyzed cohort, the proportion of patients achieving target serum phosphorus levels ≤4.5 mg/dL increased by >50% after switching to SO therapy; reductions were seen at all follow-up timepoints.
- Baseline pill burden was 8.5 pills/day. During treatment with SO, patients experienced an average 50% reduction in pill burden compared to baseline (P<0.001 for each interval vs baseline).
Illuminating the Decision-Making Process
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in the clinical setting. The researchers analyzed medical records of members of a cohort of VA patients with advanced CKD who opted not to initiate dialysis. Results of the analysis were reported online in JAMA Internal Medicine [doi:10.1001/jama. internalmed.2018.6197].

The study included electronic medical records of 851 adults receiving care from the US Veterans Health Administration between January 1, 2000, and October 1, 2011. All of the 851 patients had chosen not to start dialysis. The analysis was performed between March 1, 2017, and April 1, 2018.

Of the 851 patients, 842 were men and nine were women, mean age was 75.0 years, and 66.6% (n=567) were white. Median follow-up was 0.5 years; during follow-up 95.4% (n=812) of the cohort died and 38.0% (n=323) enrolled in hospice. Those with advanced CKD in which dialysis serves to clarify patients’ preferences and confirm competency over time; in other cases the questioning became a source of frustration and even hostility for some patients.

The repeated questioning was often prompted by transitions of care and might not lengthen life, particularly in the context of specific patient characteristics such as advanced age and disability.

HAving little to Offer Beyond Dialysis

Once clinicians recognized that patients would not be initiating dialysis, documentation in the medical records suggests that the clinicians felt they had few options to offer the patient. A few nephrology clinicians offered to continue actively monitoring patient care or to make themselves available on an as-needed basis. The more common notion indicated that the nephrology team had nothing more to offer the patient and signed off on care.

The decision not to start dialysis also tended to shut down other treatment options or interventions that might accelerate the loss of remaining kidney function, such as surgery and cardiac catheterization. Patients in the population opting not to initiate dialysis were often described as eligible or candidates for hospice care; enrollment in hospice was encouraged. Some patients (or their families) readily agreed to enter hospice care; however, many were resistant to entering hospice care and were not ready to do so until their condition deteriorated substantially.

The researchers cited some limitations to the study, including the findings not being generalizable to populations not well represented in the VA, such as women; limitations of what can be learned from medical records; complexity of the identified themes; and follow-up ending in 2011, creating the possibility that results do not represent contemporary practices.

In conclusion, the researchers said, “This study of a national cohort of patients with advanced CKD not treated with dialysis provides an important window on decision making regarding dialysis in a large US health system. Our findings describe an all-or-nothing approach to care for patients with advanced CKD in which dialysis serves as a powerful default with few perceived alternatives. Regardless of whether patients had to resist clinicians’ recommendations to undergo dialysis or were not considered candidates for dialysis, their goals and values did not seem to figure prominently in the decision-making process. Collectively, these findings call for stronger efforts to develop more patient-centered models of care for patients with advanced CKD with the capacity to proactively support those who do not wish to pursue dialysis.”

TAKEAWAY POINTS

- Some patients with advanced chronic kidney disease (CKD) opt not to initiate dialysis. Researchers conducted a qualitative study to describe how those decisions are reached in the clinical setting.
- Electronic medical records of 851 adults with advanced CKD who opted not to pursue dialysis were examined: the patients were receiving care in the US Veterans Health Administration system.
- Three major themes emerged: (1) dialysis as the norm; (2) patient not a candidate for dialysis; and (3) having little to offer beyond dialysis.

PATIENT NOT A CANDIDATE FOR DIALYSIS

There was a difference observed in the dynamic at play in situations where clinicians did not consider patients to be candidates for dialysis. Notes in the medical records routinely included language regarding whether patients were candidates or appropriate for dialysis. Such questions arose when there was a concern that dialysis might not lengthen life, particularly in the context of specific patient characteristics such as advanced age and disability.

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The unadjusted incidence rate of AF was 186.6 per 1000 person-years in the peritoneal dialysis group and 372.0 per 1000 person-years in the hemodialysis group.

Overall, median age of the cohort was 75 years, 51% were women, 73% were white, 23% were black, and 8% were Hispanic. Patients in the peritoneal dialysis cohort were younger, more likely to be male and white, had fewer comorbidity conditions, and were less likely to be impaired in their ambulation or ability to transfer. Hemodialysis patients had fewer visits with nephrologists prior to initiation of dialysis therapy as well as lower serum albumin concentrations. Overall follow-up was an average of 1.5 years, contributing 406,225 person-years. During follow-up, 69,705 participants had newly diagnosed AF. In the first months following the index date, individuals in the peritoneal dialysis group had lower unadjusted rates of AF; the differences narrowed over the remaining follow-up to 36 months. The unadjusted incidence rate of AF was lower among the peritoneal dialysis group compared with the hemodialysis group (152.0 vs 173.2/1000 person-years). The difference was confirmed by formal Cox regression models (multivariable-adjusted cause-specific hazard ratio [HR], 0.96; 95% confidence interval [CI], 0.93-0.99; subdistribution HR, 0.92 [95% CI, 0.89-0.95]). However, because the proportionality assumption was violated, the researchers conducted analyses by separating follow-up time into two periods at 3 months (<90 days vs >90 days), and including an interaction term between modality and time into the model. There was no residual violation of the proportionality assumption observed within either of the two periods.

A total of 21,709 patients developed incident AF during the first 3 months of dialysis therapy, and 22,241 patients without AF died. The unadjusted incidence rate of AF was 186.6 per 1000 person-years in the peritoneal group and 372.0 per 1000 person-years in the hemodialysis group. Estimates of association from the cause-specific model suggested that patients on peritoneal dialysis therapy had an adjusted 43% (95% CI, 38%-47%) lower incidence of AF compared with those on hemodialysis therapy. From month 4 onward, 224,176 patients were followed for incident AF. During up to 33 additional months of follow-up, there were 47,996 incident events over 345,276 person-years. In the peritoneal dialysis group, the unadjusted rate of AF incidence was 145.2 per 1000 person-years; in the hemodialysis therapy group, the unadjusted rate was 138.6 per 1000 person-years. After controlling for all demographic and recorded health-related characteristics and comorbidity conditions, the multivariable-adjusted cause-specific HR for peritoneal dialysis versus hemodialysis was 1.14 (95% CI, 1.10-1.19). After accounting for the competing risk for death, the difference in the risk for incident AF between the two groups essentially disappeared (subdistribution HR, 1.05 [95% CI, 1.01-1.09]).

Study limitations included the observational design of the study; possible confounding due to unobserved differences between exposure groups; ascertaining incidence of AF from billing claims; and the possibility that the findings may not be generalizable to younger patients. In conclusion, the researchers said, “We found that AF incidence differed between older patients initiating dialysis therapy using peritoneal dialysis versus hemodialysis in the United States, specifically that patients using hemodialysis had increased AF risk during the first 3 months. Thereafter, the adjusted incidence of AF was similar between patients receiving hemodialysis versus peritoneal dialysis. This study highlights the opportunity to further investigate the high rate of mortality, in particular as it related to arrhythmia, in patients with ESRD new to dialysis therapy.”

**TAKENAWY POINTS**

- Researchers conducted a retrospective cohort study to determine whether there is a difference in incidence of atrial fibrillation (AF) between patients with incident end-stage renal disease receiving hemodialysis and those receiving peritoneal dialysis.
- During the first 3 months of dialysis therapy, patients on peritoneal dialysis had an adjusted 39% lower incidence of AF compared with patients on hemodialysis.
- From day 91 onward, the incidence of AF was ~140 per 1000 person-years; there were no differences between the two modality groups.

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**Use of a Patient Portal Decreases Hospital Admission Rates**

San Diego—Clinical status of patients on peritoneal dialysis are commonly assessed only once a month, limiting the clinician’s view of the state of the patient’s health. A large dialysis provider has launched a connected health program to enable patients on peritoneal dialysis to enter their clinical parameters or concerns daily. The portal provides automated alerts to clinicians for abnormal findings; patient nonadherence to reporting also triggers an alert to the clinician.

Carlos Muchiutti and colleagues at Fresenius Medical Care North America, Waltham, Massachusetts, recently conducted a comparison of outcomes (hospital admissions and modality failure) between patients using the portal and patients not using the portal. Results of the comparison were reported during a poster session at Kidney Week 2018 in a poster titled “Association Between Use of a Patient Portal with Hospitalization Rates and Modality Failure in Peritoneal Dialysis Patients.”

The comparison included data on 5549 active peritoneal dialysis patients who were introduced to the patient portal prior to September 30, 2017. Inclusion criteria were ≤10 hospitalization days in September 2017. The engaged group was defined as those who documented data for ≥20 hospitalizations during September 2017 (n=1199). The remaining 4350 patients did not document any treatment data on the portal and were defined as the non-engaged group. Patients who documented data on ≥20 treatments were excluded from the analysis. Follow-up continued for 6 months starting September 30, 2017, until the earliest discharge date from the clinic (including death). Transition from peritoneal dialysis to hemodialysis, or the end of the follow-up period. Chi-square test was used to compare the percent of patients who transitioned from peritoneal dialysis to hemodialysis without accounting for the length of follow-up. Poisson regression model, adjusted for prior hospitalizations, was used to compare the hospitalization rate during the follow-up period. There was a 20% lower risk of hospitalization in the engaged group compared with the non-engaged group (relative risk, 0.8; P=0.001). There was no significant difference in modality changes from peritoneal dialysis to hemodialysis between the two groups (17% engaged patients vs 16% non-engaged patients; P=0.1).

In conclusion, the researchers said, “Consistent documentation of treatment data in the patient portal was associated with lower hospital admission rates among peritoneal dialysis patients, suggesting that better patient engagement as well as more real-time clinician involvement may impact patients’ hospitalization rates. However, observations may be confounded by indication of portal use, which could represent a more adherent group of patients. Further analysis is needed to confirm these findings.”

The American College of Cardiology held its 68th Annual Scientific Session, ACC.19, March 16–18, 2019, in New Orleans. During poster sessions on March 16 and 17, researchers presented new kidney research on (1) the association between the misuse of medications to treat atrial fibrillation in patients with chronic kidney disease and (2) the higher risk for adverse cardiovascular events faced by patients with stage 5 chronic kidney disease and untreated periodontal disease.
Periodontal Disease and Risk of Major Cardiovascular Events in Patients with Stage 5 CKD

New Orleans—Patients with stage 5 chronic kidney disease (CKD) are at increased risk for mortality due to cardiovascular disease morbidity. Patients with stage 5 CKD also have a high prevalence of periodontal disease. There are few data available on whether the rate of major cardiovascular events in patients with CKD stage 5 may be decreased with periodontal examination and treatment of incidentally found periodontal disease.

Jose Lima, MD, and colleagues conducted an analysis to test that hypothesis in a cohort of patients with CKD stage 5. Results of the analysis were reported during a poster session at ACC.19 in a poster titled “Treatment of Periodontal Disease Significantly Affects the Rate of Cardiovascular Events in Patients with Chronic Kidney Disease.”

The analysis included 409 patients with CKD stage 5. The patients were stratified into two groups: patients who underwent periodontal examination and treatment of periodontal disease by debridement and/or tooth extraction (intervention group, n = 206) were compared with a group of patients who did not undergo periodontal examination (historical control group, n = 203). Follow-up continued for 24 months or until death or kidney transplantation.

In the patients in the periodontal examination/treatment group, the prevalence of moderate-to-severe periodontal disease was 74%. Compared with the historical control cohort, patients in the intervention group were younger (52.6 years vs 55.2 years; P = .02), and had longer duration on dialysis (24 months vs 17 months; P = .01). Patients in the intervention group also had higher event-free survival rates of major cardiovascular events (94% vs 83%; P = .009), coronary events (97% vs 89%; P = .009), and cardiovascular death (96% vs 87%; P = .037). There was no difference between the two groups in rates of all-cause death.

Results of multivariate analyses by Cox proportional hazard models adjusted for age, sex, smoking status, dyslipidemia, diabetes, cardiovascular disease, time on dialysis, and previous coronary intervention demonstrated associations between periodontal examination and treatment of periodontal disease and reduction in cardiovascular events [hazard ratio (HR) 0.43; 95% confidence interval (CI), 0.22-0.87; P = .019], coronary events (HR 0.31; 95% CI, 0.12-0.83; P = .02), and cardiovascular death (HR 0.43; 95% CI, 0.19-0.98; P = .045). Smoking was not a predictor of cardiovascular death [HR 1.31, 95% CI, 1.09-1.58; P = .01].

In summary, the authors said, “The prevalence of periodontal disease in patients with CKD stage 5 is high. Periodontal examination and treatment of incidentally found periodontal disease reduced the 24-month risk of major cardiovascular events, including coronary-related events and cardiovascular death but not all-cause mortality. We suggest a specific role of periodontal disease on cardiovascular prognosis in patients on dialysis. Based on our data, we propose that periodontal disease should be routinely screened for (and treated accordingly) in patients with CKD stage 5.”


In the patients in the periodontal examination/treatment group, the prevalence of moderate-to-severe periodontal disease was 74%. Compared with the historical control cohort, patients in the intervention group were younger (52.6 years vs 55.2 years; P = .02), and had longer duration on dialysis (24 months vs 17 months; P = .01).

Underuse of Oral Anticoagulation and Overuse of Aspirin in Atrial Fibrillation Patients with CKD

New Orleans—There is an association between renal function and outcomes of patients receiving anticoagulation treatment for atrial fibrillation. Michael Dorsch, MS, PharmD, and colleagues conducted an analysis to test the hypothesis that there are changes in prescribing patterns of oral anticoagulants and clinical outcome based on chronic kidney disease (CKD) status. Results of the analysis were presented during a poster session at ACC.19 in a poster titled “Oral Anticoagulation Underused and Aspirin Overused for Atrial Fibrillation with Advanced Chronic Kidney Disease Status.”

The analysis included patients from the Premier Health Database. Inclusion criteria were age ≥40 years, hospital admission from January 2011 to June 2015 with a diagnosis of atrial fibrillation, CHADS2-VASc (congestive heart disease, age, diabetes, stroke, vascular disease) score >2, length of stay >1 day and CKD stage >1. Exclusion criteria were presence of a mechanical heart valve, any bleed or major surgery during admission, departure from the hospital against medical advice, hospice admission, transfer to another acute care facility, or died during index admission.

The primary outcomes of interest were bleeding, ischemic stroke, and mortality at 1-year post index admission. In the 797 US hospitals in the Premier Health system, there were 370,672 admissions with a diagnosis of atrial fibrillation during the study period. Of those, mean age was 78 years and 45% used oral anticoagulation agents. There was a strong association between oral anticoagulation use and CKD status.

Patients with advanced stages of CKD had the lowest use: use among patients with CKD stage 1 was 49.1% versus 36.4%, among patients with end-stage CKD. The decrease was due primarily to a decrease in direct oral anticoagulation (18.7% vs 2.2%) and an increase in aspirin use (17.7% vs 25.7%) as CKD progressed.

In conclusion, the researchers said, “More advanced CKD status was associated with lower oral anticoagulation use and higher aspirin use. CKD status was associated with differential effects on bleeding, with direct oral anticoagulation therapy having lower 1-year bleeding compared to warfarin in CKD stage 4 to end stage. Direct oral anticoagulation consistently reduced 1-year mortality compared to warfarin.”

Limiting Interdialytic Weight Gain in Patients on Hemodialysis

Many patients on chronic hemodialysis therapy exceed the recommended values of interdialytic weight gain (IDWG) of 4.0% to 4.5% of dry weight; some have IDWG of 10% to 20%. There are associations between higher IDWG and increased risk of all-cause and cardiovascular death. IDWG has also been shown to be a risk factor for increased morbidity, including ventricular hypertrophy and major adverse cardiac and cerebrovascular events. IDWG can also create the need for supplementary weekly dialysis sessions, with subsequent negative affect on quality of life and healthcare costs.

High IDWG is secondary to excessive intake of fluids and/or foods. An estimated 30% to 60% of patients on hemodialysis do not adhere to a fluid intake regimen. Thirst and xerostomia (the subjective feeling of a dry mouth) are the leading causes of poor adherence to fluid restriction.

Current clinical practice utilizes various strategies to limit IDWG. Maurizio Bosso-la, MD, and colleagues recently presented a review article evaluating the efficacy of the strategies used in routine clinical practice and tested in clinical trials. The review was published in the Journal of Renal Nutrition [2018;28(5):293-301].

Relevant studies up to October 2014 were identified using Medline, PubMed, Web of Science, and the Cochrane Library. The search terms used were hemodialysis OR dialysis AND weight gain OR interdialytic OR interdialytic weight gain OR thirst OR xerostomia OR dialysate OR sodium dialysate concentration. A total of 470 manuscripts were reviewed and 81 were included in the current review.

The basis for the strategy to limit IDWG is reduction of thirst and improvement of motivation and knowledge to increase adherence to fluid restriction. Interventions used to reduce thirst in patients on chronic hemodialysis are reduction of dietary salt intake, improvement of xerostomia, and the use of lower dialysate sodium concentration.

Guidelines from the National Kidney Foundation Kidney Disease Outcomes Quality Initiative note that “Advising patients to limit their water intake without curtailing their salt intake will cause suffering from unnecessary thirst. Some of these patients may even feel guilty if they fail to resist the urge to drink in the face of marked thirst.”

Patients on chronic hemodialysis therapy should restrict salt intake to no more than 5.0 g/day (2 g of sodium). The estimated average daily salt intake among dialysis patients may range from 7.9 to 14.1 g/day. There are geographic variations in salt intake of hemodialysis patients; salt intake is higher in areas where the diet is rich in processed foods.

Factors that contribute to poor adherence to salt restriction include lack of knowledge, interference with socialization, and lack of food selections. Patients with poor adherence have lower education level and lower socioeconomic status compared with patients with improved adherence.

Overall, two strategies have been used to reduce salt intake: (1) prescription of a diet with low salt content; or (2) nutritional counseling. Results of a 1997 study indicated that nutritional counseling and social cognitive theory-based behavioral counseling did not reduce dietary salt intake or IDWG; in a randomized controlled study, 2 g of sodium restriction on patients’ habitual diet did not reduce IDWG. Two small 1999 studies did show that adherence to a low-salt diet was reliable and associated with reduced IDWG, and a 48-month program of nutritional counseling resulted in a significant decrease of salt and water intake as well as of IDWG. “Overall, it seems that efforts should be made to design adequate, randomized controlled studies to determine if salt restriction may reduce IDWG and define the entity of such restriction in terms of grams per day,” the review authors said.

Behavioral interventions designed to improve adherence to fluid restriction have been based on a variety of approaches, including behavioral contracting and weekly telephone contacts with patients, patient self-monitoring and behavioral contracting upon adherence. Stepped verbal and written reinforcement, group-administered behavioral self-regulation intervention, group education sessions based on transtheoretical model (states of change), self-efficacy training, and group or individual cognitive behavioral therapy. Results of trials testing those models have not produced clear conclusions regarding their efficacy.

At present, there is no valid therapy for xerostomia in patients receiving chronic hemodialysis therapy. There have been three studies designed to assess the effect of sugarless chewing gum on hemodialysis patients with xerostomia; however, the three studies had conflicting results.

In a randomized crossover study, the use of sugarless gum was compared with use of a saliva substitute for 6 weeks. There was significant reduction in xerostomia in patients in the sugarless gum group, and both treatments significantly reduced thirst; there were no differences in IDWG between the two groups. In contrast, a study conducted in a cohort of 38 chronic hemodialysis patients with regular use of sugarless gum for 3 months did not result in alleviation of xerostomia or reduction of IDWG. Results from another recent randomized controlled study demonstrated that chewing gum for 15 minutes each hour during a hemodialysis session was ineffective in increasing salivary flow and improving xerostomia.
Chronic kidney disease (CKD) is defined by abnormalities in glomerular filtration rate (GFR) and/or albuminuria; CKD affects approximately 10% of the US population. Endogenous plasma or serum filtration markers, most commonly creatinine, are used to estimate GFR; albuminuria is quantified by measuring urinary albumin concentration (UAC) or urinary albumin-creatinine ratio (UACR). There are well established reference ranges for estimated GFR (eGFR) and albuminuria in healthy individuals.

For patients with CKD, determining the clinical significance of a change in eGFR or albuminuria requires knowledge of the expected variability in the absence of underlying clinical changes. However, there are relatively few data on the inherent biologic variability of eGFR and UACR in the setting of CKD.

Sushrut S. Waikar, MD, MPH, and colleagues, on behalf of the Chronic Kidney Disease Biomarkers Consortium Investigators, recently conducted a cross-sectional study to provide estimates of the short-term within-person biologic variability in measures of kidney function, including albuminuria (UAC and UACR) and plasma eGFR markers (creatinine and cystatin C, β2-microglobulin [B2M], and beta trace protein [BTP]). Study results were reported in the American Journal of Kidney Diseases [2018;72(4):538-546].

Examining Short-Term Within-Person Variability in Clinical Markers of Kidney Function

Researchers conducted a literature search to assess the efficacy of current strategies used to limit interdialytic weight gain (IDWG) in patients on chronic hemodialysis. A low-salt diet is effective; however, it is associated with poor adherence. Treatment of xerostomia offers a promising path to reduction of IDWG, but a valid therapy is still lacking. The use of individualized sodium dialysate seems a promising strategy. Behavioral interventions aimed at improving adherence to fluid restriction have led to encouraging—albeit short-term—results. Nevertheless, experimental and innovative treatments are lacking. It seems that research efforts should focus on a better understanding of the mechanisms of thirst and xerostomia as well as on an improvement of their management. Further clinical investigations should be made also in individualized sodium dialysate. The scientific and clinical communities should gain complete awareness of the problem and try to find an adequate and rapid remedy.

**TAKEAWAY POINTS**

- Researchers conducted a literature search to assess the efficacy of current strategies used to limit interdialytic weight gain (IDWG) in patients on chronic hemodialysis.
- A low-salt diet is effective; however, it is associated with poor adherence. Treatment of xerostomia offers a promising path to reduction of IDWG, but a valid therapy is yet to be developed.
- Gradual reduction of sodium dialysate concentration has been shown to be effective in reducing IDWG in this patient population in a recent small longitudinal study.

In summary, the authors said, “It is still difficult to limit IDWG in patients on chronic hemodialysis. The therapeutic strategies used so far have shown to be of limited efficacy in terms of size and duration. The low-salt diet is effective, but unfortunately, it is characterized by poor adherence. Xerostomia represents an important target to reduce IDWG, but a valid therapy is still lacking. The use of individualized sodium dialysate seems a promising strategy. Behavioral interventions aimed at improving adherence to fluid restriction have led to encouraging—albeit short-term—results. Nevertheless, experimental and innovative treatments are lacking. It seems that research efforts should focus on a better understanding of the mechanisms of thirst and xerostomia as well as on an improvement of their management. Further clinical investigations should be made also in individualized sodium dialysate. The scientific and clinical communities should gain complete awareness of the problem and try to find an adequate and rapid remedy.”
Study participants were clinically stable outpatients with CKD (n=50) attending a nephrology subspecialty practice at Brigham and Women’s Hospital, Boston, Massachus-
Vascular Access Selection in Elderly Patients Involves Tradeoffs

For patients receiving maintenance hemodialysis, vascular access provides a critical conduit for the delivery of blood to the extracorporeal circuit. More than 80% of patients initiating hemodialysis in the United States do so with a central venous catheter (CVC); most then undergo placement of a permanent vascular access, either an arteriovenous fistula (AVF) or graft (AVG). Until the AVF or AVG can be successfully used for dialysis, patients remain catheter dependent; there is an association between longer duration of dependence on a CVC and increased risk for catheter-related bacteremia and mortality.

Recommendations from the Fistula First Initiative, launched by the Centers for Medicare & Medicaid Services in 2002, call for providers to maximize AVF use in preference to an AVG, because AVFs have long-term survival compared with that of AVGs and fewer interventions are required to maintain such patency. Timmy Lee, MD, MSPH, and colleagues previously compared outcomes (mortality and hospitalizations) in a national cohort of elderly patients who initiated dialysis therapy with a CVC and then had an AVF or AVG placed. That study found an association between the placement of an AVF and greater patient survival despite longer dependence on a CVC. The researchers recently conducted a retrospective cohort study designed to compare several clinically relevant outcomes related to vascular access type in the same cohort and to better understand the tradeoffs between AVF and AVG selection in that patient population. Results were reported in the American Journal of Kidney Diseases [2018;72(4):509-518].

The outcomes of interest were successful use of vascular access, interventions to make vascular access functional, duration of catheter dependency prior to successful vascular access use, frequency of interventions, and abandonment after successful use of vascular access. Comparison of the need for intervention prior to successful use of AVFs and AVGs was determined using multivariable logistic regression analysis; the frequency of intervention after successful use of vascular access was calculated using binomial regression. The researchers also calculated the adjusted odds ratios (ORs) or relative risks (RRs) of those outcomes for patients receiving an AVF versus an AVG.

The original cohort included 46,634 patients ≥67 years of age who initiated hemodialysis therapy from July 1, 2010,
to June 30, 2011. Of those patients, 29,178 initiated hemodialysis with a CVC only, without an AVF or AVG placed in the pre-ESRD period, awaiting successful use. Application of other exclusion criteria (no pre-ESRD Medicare claims; with pre-ESRD AVF/AVG surgeries; no AVF/AVG within 6 months of initiation of dialysis therapy; and/or received a kidney transplant or switched to peritoneal dialysis), resulted in a final cohort for the current study of 9458 elderly patients who received an AVF (n=7433) or AVG (n=2025) in the 6 months following initiation of hemodialysis therapy.

Compared with the patients receiving an AVG, those in the group with an AVF creation were younger, had a greater proportion of men and whites, had a lower Liu comorbidity index score, and was less likely to have a history of stroke, peripheral vascular disease, and chronic obstructive pulmonary disease. Patients in the AVF group also had fewer hospital days in the 6 months prior to hemodialysis therapy initiation. Both groups had similar duration of catheter dependence from the time of dialysis initiation to vascular access placement (~10 weeks).

In the 6 months following placement, a higher proportion of AVFs than AVGs failed to be used successfully for dialysis (51% vs 45%; adjusted hazard ratio [HR], 1.86; 95% confidence interval [CI], 1.73-1.99). A substantial proportion of vascular accesses required an intervention to make the vascular access functional. A higher proportion of patients in the AVF group required an intervention to make their access functional, compared with patients in the AVG group (42% vs 23%; OR, 2.66; 95% CI, 2.26-3.12).

In the group requiring interventions to make AVFs functional, the median duration of catheter dependence following vascular access creation and prior to first use was greater than in those who did not require interventions (4 vs 3 months; P < .001). It was also greater in patients with AVGs who required interventions for successful access use compared with no interventions required (2 vs 1 months; P < .001). Among patients with interven-
Researchers conducted a retrospective cohort study using national data to examine clinically relevant vascular access outcomes in elderly patients receiving an arteriovenous fistula (AVF) or graft (AVG).

The analysis revealed tradeoffs in that patient population regarding the two types of vascular access: AVG placement favored shorter duration of catheter use and minimized the need for interventions to make the vascular access functional. In contrast, AVF placement favored a longer lasting vascular access with fewer maintenance interventions.

TAKEAWAY POINTS

- In the group requiring interventions to make AVFs functional, the median duration of catheter dependence following vascular access creation and prior to first use was greater than in those who did not require interventions (4 vs 3 months; $P < .001$).

- The analysis revealed tradeoffs in that patient population regarding the two types of vascular access: AVG placement favored shorter duration of catheter use and minimized the need for interventions to make the vascular access functional.

- In contrast, AVF placement favored a longer lasting vascular access with fewer maintenance interventions.

In summary, our study demonstrates clear tradeoffs among elderly patients who initiate hemodialysis therapy with a catheter and have a subsequent permanent vascular access placed. Compared with AVGs, AVFs are less likely to have successful use after creation, more likely to require interventions to make them functional, and are associated with longer catheter dependence. In contrast, AVFs require fewer interventions to maintain patency after successful use and experience fewer abandonments in the first year after successful use. Ultimately, when considering selection and placement of the best vascular access in elderly patients initiating hemodialysis therapy with a catheter, the clinician must balance the importance of removing the catheter and minimizing the need for interventions to make the vascular access functional (favoring AVG placement) versus a longer lasting vascular access with fewer maintenance interventions (favoring AVF placement).
Over the past 15 years, the United States has seen demographic, social, and epidemiologic changes; there have also been substantial increases in measures of sociodemographic development and exposure to risk factors for chronic kidney disease (CKD) over the same period.

To date, there has not been a detailed quantitative analysis of the change in burden of CKD. Benjamin Bowe, MPH, and colleagues recently conducted an analysis of data from the 2016 Global Burden of Disease study in the United States; in addition, the researchers examined data on CKD from 2002 to 2016 at the state level. The analysis was designed to (1) describe the change in the burden of CKD in the United States from 2002 to 2016, (2) characterize the factors associated with change in the CKD burden, and (3) examine the ways sociodemographic progress has shaped the burden of CKD. Results were reported online in JAMA Network Open [doi:10.1001/jamanetworkopen.2018.4412].

The primary outcomes and measures of interest were disability-adjusted life years (DALYs) and death due to CKD.

CKD DALYs in the United States increased from 1,269,049 in 2002 (95% uncertainty interval [UI], 1,154,521-1,387,008) to 1,935,954 in 2016 (95% UI, 1,747,356-2,124,795), for a 52.6% increase over the 15-year study period. There was an increase in DALY rates of 35.9%, from 441 per 100,000 population (95% UI, 401-482/100,000 population) in 2002 to 600 per 100,000 population (95% UI, 541-658/100,000 population) in 2016.

DALY rates standardized by age increased from 371 per 100,000 population (95% UI, 336-406/100,000 population) in 2002 to 440 per 100,000 population (95% UI, 395-485/100,000 population) in 2016, an increase of 18.6%. An analysis of the change in age-standardized DALY rates by four causes of CKD (diabetes, hypertension, glomerulonephritis, and other) demonstrated an increase in the age-standardized DALY rate of CKD due to diabetes (21.8%), CKD due to hypertension (22.0%), CKD due to glomerulonephritis (10.4%), and CKD due to other causes (10.3%). In the overall United States, there was an increase in deaths due to CKD from 52,127 (95% UI, 51,082-53,076) in 2002 to 82,539 (95% UI, 80,298-84,652). In 2002, there were 18 deaths from CKD per 100,000 population; in 2016, there were 26 deaths per CKD per 100,000 population, an increase of 41.1%. During the 15-year study period, the age-standardized death rate increased by 17.9%, from 14 per 100,000 population to 16 per 100,000 population. The age-standardized death rates for CKD due to diabetes increased by 20.0%, hypertension by 19.8%, glomerulonephritis by 11.1%, and other causes by 11.0%.

In analyses of data at the state level, the states with the highest age-standardized DALY rates per 100,000 people in 2016 were (in descending order): Mississippi (697); Louisiana (681); Alabama (604); West Virginia (587); Georgia (560); Arkansas (553); South Carolina (550); Kentucky (550); Indiana (515); and North Carolina (515). The states with the lowest age-standardized DALY rates per 100,000 population were (in ascending order): Vermont (321); Washington (328); Colorado (331); Montana (333); Oregon (342); Wyoming (343); New Hampshire (343); Iowa (349); Rhode Island (355); and Connecticut (356). The state with the highest burden, Mississippi, had twice the age-standardized CKD DALY rate compared with Vermont (the state with the lowest burden).

All states exhibited an increase in CKD DALYs from 2002 to 2016, but there was a difference in the magnitude of the increase, ranging from 32.9% in Oklahoma to 6% in Nevada. The states with the largest increase in age-standardized CKD DALY rates were (in descending order): Alaska (102.7%); New Mexico (96.8%); Nevada (95.3%); and Colorado (94.9%). Those with the least increase in age-standardized CKD DALY rates were (in ascending order): Nevada (5.6%); New Jersey (6.8%); Massachusetts (8.8%); Maryland (9.3%); Illinois (10.4%); New York (10.8%); Connecticut (11.3%); Pennsylvania (12.0%); Georgia (12.7%); and Colorado (13.6%). There was variation in age-standardized death rates among states in 2016. Rates were 2.4-fold higher in Louisiana compared with Vermont (28/100,000 population vs 11/100,000 population, respectively). From 2002 to 2016, the rate of change in age-standardized deaths varied among states and ranged from 41.0% in Iowa to –2.8% in Nevada.

During the study period, there was a 52.6% increase in DALYs in the United States, of which 40.3% was attributable to increased risk exposure, 32.3% to aging, and 27.4% to population growth. The rates increased by 18.6% where increases in metabolic, and to a lesser extent dietary, risk factors contributed 93.8% and 5.23% of the change, respectively.

Diabetic CKD was the primary contributor to the 26.8% increased probability of death due to CKD among those 20 to 54 years of age; among those 55 to 89 years of age, the probability of death due to CKD increased by 25.6% and was driven by CKD due to diabetes and decreased probability of death from causes other than CKD. Improvement in sociodemographic development was coupled with an increase in age-standardized CKD DALY rates that occurred at a faster pace than that of other noncommunicable diseases in the United States.

The researchers cited some limitations to the study, including limiting analyses to state-level data; attributing CKD to a single cause; and restricting analysis in the change in probability of death to persons >20 years of age while not restricting all other analyses to the adult population.

“Our study revealed that, from 2002 to 2016, the burden of CKD in the United States increased and was variable among states. This increase may be associated with increased risk exposure and demographic expansion leading to increased probability of death from CKD, especially among young adults. The findings suggest that an effort to target the reduction of CKD through greater attention to metabolic and dietary risks, especially among younger adults, is necessary,” the researchers said.
Dietary Implications Renal Impairment and Levels of Toxic Metabolites

According to Michael Pignanelli, BMSc, and colleagues, variations in atherosclerosis burden can only be partly explained by traditional risk factors for coronary heart disease (CHD), and genetic variants may account for only 10.6% of heritability of CHD. Following treatment with usual care for traditional risk factors, the risk of cardiovascular events remains approximately 40%.

There is an independent association between renal impairment and cardiovascular mortality, and current treatments of renal failure have been shown to have limited efficacy in preventing cardiovascular deaths. Patients with chronic kidney disease (CKD) are at high risk for cardiovascular disease. Previous studies have found an increase of 17-fold in the risk of cardiovascular disease in patients with end-stage renal disease, and a marked reduction in life expectancy at age 55: from 19.9 years with normal or only slightly impaired renal function to 5.6 years with severe renal impairment.

There are adverse cardiovascular disease effects of toxic metabolites produced by the intestinal microbiome from animal proteins, carnitine (primarily from red meat), or phosphatidylcholine (primarily from egg yolk). The metabolites are eliminated renally and may be termed gut-derived uremic toxins (GDUT). The current cohort study was designed to examine plasma levels of GDUT in relation to renal function to test the hypothesis that even moderate impairment of renal function may increase the levels of GDUT. Results of the study were reported in the Journal of Renal Nutrition [2019;29(1):SS-64].

Nutrient intake was measured by the 131-item Harvard Food Frequency Questionnaire; estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease-Epidemiology equations. Ultra-performance liquid chromatography coupled to quadrupole time-of-flight mass spectrometry was used to measure plasma levels of trimethylamine N-oxide, p-cresyl sulfate, hippuric acid, p-cresyl glucuronide, phenyl acetyl glutamine, and phenyl sulfate. A total of 316 patients were enrolled in the study. Mean age was 66.74 years, 59.7% were men, and 18.9% were diabetic. Mean eGFR was 76.03 mL/min/1.73 m²; 18% (n = 57) had eGFR < 45 mL/min/1.73 m².

Participants were stratified into quartiles by eGFR: (Q1, < 66 mL/min/1.73 m²; Q2, 66 to 78 mL/min/1.73 m²; Q3, 79 to 90 mL/min/1.73 m²; and Q4, ≥ 91 mL/min/1.73 m²). Plasma levels of all GDUT were significantly lower by quartile of eGFR, even with moderate reduction of eGFR, plasma levels of all GDUT were significantly higher in those quartiles. Plasma levels of some GDUT were affected by nutrient intake; the effects varied by eGFR above and below 60 mL/min/1.73 m².

In linear regression analyses, eGFR was a significant predictor for all of the metabolites. In general, intake of meat/amino acids contributed to the plasma levels of all of them. Levels of hippuric acid were explained primarily by intake of vegetable protein and precursors of crude trimethylamine (pre-TMA). Intake of chlorine/pre-TMA, largely from egg yolk, contributed significantly to plasma levels of trimethylamine N-oxide, hippuric acid, and p-cresyl glucuronide.

There were no differences detected in the intestinal bacteria across carotid ultrasound phenotypes.

Citing limitations to the study, the researchers mentioned obtaining blood samples in fasting conditions and not including vegans in the study cohort.

“Patients with even moderately impaired renal function (including the elderly) should limit intake of meat, particularly red meat because of the high carnitine content, and should avoid egg yolk, not only because of the very high cholesterol content (237 mg in a 65-g egg) but also because of the high content of phosphatidylcholine (250 mg). Two large egg yolks would contain more cholesterol and more trimethylamine N-oxide precursor than a 12-ounce Hardee’s Monster Thickburger, with 256 mg of cholesterol and 320 mg of carnitine,” the authors said.

Post Hoc Analysis: Patiromer Safe and Effective in Patients with Diabetes Mellitus

San Diego—Researchers, led by Patrick Rossignol, MD, PhD, recently conducted a post-hoc pooled analysis to examine the efficacy and safety of patiromer for the treatment of hyperkalemia in patients with and without diabetes mellitus. The researchers reported results of the analysis during a poster session at Kidney Week 2018 in a poster titled Efficacy and Safety of Patiromer in Participants with Diabetes: A Pooled Analysis.

Pooled data through week 4 from three trials of patiromer were analyzed. The data included participants who took more than one dose of patiromer and had more than one post-baseline serum potassium measurement. The participants were stratified based on the presence or absence of diabetes, and were assessed for (1) change in serum potassium from baseline at week 4, (2) serum potassium over time, and (3) percent with any serum potassium measurement in the target range of 3.8 to 5.0 mEq/L.

The analysis included 653 participants; 82% had diabetes; mean baseline hemoglobin A1c was 7.4%, and mean duration of diabetes was 14 years. In the patients with diabetes, mean baseline serum potassium was 5.4 mEq/L and estimated glomerular filtration rate (eGFR) was 40.3 mL/min/1.73 m²; in patients without diabetes the values were 5.5 mEq/L, and 34.8 mL/min/1.73 m² respectively.

At week 4, overall mean change from baseline in serum potassium was -0.72 in the diabetes group and -0.88 in participants without diabetes. Among participants with baseline serum potassium >5.5 mEq/L, mean serum potassium changes at week 4 were -1.01 in those with diabetes and -1.12 in those without diabetes. Among those with baseline serum potassium ≤5.5 mEq/L, the changes were -0.52 in participants with diabetes and -0.51 in participants without diabetes.

Regardless of serum potassium status at baseline, 95% of all participants in both the diabetes group and in the group without diabetes achieved any serum potassium measurement in the target range. The results were not impacted by the presence or absence of heart failure or eGFR <45 mL/min/1.73 m².

At least one adverse event (AE) was reported by 31% of those with diabetes and 38% of those without diabetes. The most common AEs were constipation, diarrhea, hypomagnesemia, and nausea. Hypomagnesemia was reported in 2% of both groups. Lab values of magnesium of <1.4 mg/dL occurred in 5% of participants with diabetes and 1% of those without diabetes. Those who experienced low serum magnesium commonly used proton pump inhibitors and/or loop diuretics.

“In this post-hoc analysis of pooled data, patiromer was equally effective and well-tolerated in [participants with and without diabetes],” the researchers said.


This analysis was funded by Reillypsa, Inc. a Vifor Pharma Group Company.
Maternal and Fetal Outcomes in Pregnant Kidney Transplant Recipients

Due to disruption of hypothalamic gonadal axis, women with end-stage renal disease (ESRD) have impaired fertility, resulting in a very low incidence of conception in women on dialysis (range, 0.9% to 7%). In some cases, recipients of kidney transplantation experience a rapid restoration of fertility, making transplantation the optimal treatment for women with ESRD who wish to become pregnant.

There are challenges associated with pregnancy in a kidney transplant recipient, including the risk of adverse maternal complications of preeclampsia and hypertension, as well as the risk of adverse fetal outcomes of premature birth, low birth weight, and small for gestational age infants. There are also risks from the side effects of immunosuppression medication, and the risk of deterioration of allograft function. These risks call for preconception counselling, family planning, and contraception as part of the counselling process prior to transplantation.

There are limited data available on clinical outcomes of pregnancy in kidney transplant recipients. Silvi Shah, MD, and colleagues recently conducted a systematic review and meta-analysis to identify all studies of pregnancy-related outcomes in kidney transplant recipients worldwide and to estimate pooled incidence of pregnancy outcomes, maternal complications, and fetal complications.

Secondary goals included examination of the impact of pregnancy on allograft loss and allograft rejection, identification of the ideal maternal age for conception, and determination of the ideal time of conception following kidney transplantation. Results of the analysis were reported online in *BMC Nephrology* [2019; doi.org/10.1186/s12882-019-1213-5].

The researchers searched PubMed/MEDLINE, Elsevier EMBASE, Scopus, BIOSIS Previews, ISI Science Citation Index Expanded, and the Cochrane Central Register of Controlled Trials from their earliest date of inception through August 31, 2017. Key search terms used were pregnancy complications, pregnancy outcome, maternal outcome, fetal outcome, birth outcome, kidney transplant, or renal transplant. Observational studies (prospective cohort, retrospective cohort, and cross-sectional), case series, and case reports (with n >10 pregnancies) that examined pregnancy, maternal outcomes, and fetal outcomes in women ≥18 years of age who received a kidney transplant were eligible for inclusion. Studies analyzing the teratogenic effects of mycophenolate or sirolimus, and non-English language studies were excluded.

The search yielded 4134 citations. Of these, the researchers reviewed 136 full-text articles, and selected 87 to be included in the final study cohort. Three studies were from Africa, 31 from Asia, 31 from Europe, 10 from North America, four from Oceania, and eight from South America. The 87 studies represented 6712 pregnancies in 4174 kidney transplant recipients. Mean maternal age was 29.6 years and mean interval between kidney transplant and pregnancy was 3.7 years.

The outcomes included live birth rate (72.9%; 95% confidence interval [CI], 70.0-75.6), miscarriages rate (15.4%; 95% CI, 13.8-17.7), induced abortion rate (12.4%; 95% CI, 10.4-14.7), stillbirths rate (5.1%; 95% CI, 4.0-6.5), and rate of ectopic pregnancies (2.4%; 95% CI, 1.5-3.7).

Live birth rates were higher in the study cohort of kidney transplant recipients than in the general population in the United States (72.9% vs 62%); the rates were favorable across all geographic regions. Overall, the rate of miscarriage was slightly lower than in the US general population (15.4% vs 17.1%); it was higher across Africa (21.0%; 95% CI, 14.5-29.9) and South America (20.2%; 95% CI, 15.6-25.7).

The rate of induced abortion was also lower than in the general US population (12.4% vs 18.6%). South America had the highest rate of induced abortion (19.8%; 95% CI, 12.2-30.3), followed by Asia (13.3%; 95% CI, 9.6-18.3), Oceanica (11.5%; 95% CI, 9.3-14.0), North America (10.9%; 95% CI, 5.9-19.2), Europe (10.0%; 95% CI, 7.3-13.5), and Africa (7.7%; 95% CI, 1.4-32.6). In the total cohort, the rate of stillbirth was higher than in the US general population (5.1% vs 0.6%). Stillbirth rate was highest in Asia (6.6%; 95% CI, 4.8-9.0), and lowest in Africa (2.6%; 95% CI, 0.4-16.5). The rate of ectopic pregnancy was slightly higher than in the general population in the United States (2.4% vs 1.4%); the highest rate was in Asia (3.3%; 95% CI, 1.1-9.8).

Results from subgroup analyses of studies published from 2000 to 2017 for pregnancy outcomes were consistent with the current findings.

In the overall cohort, the rate of pre-eclampsia was 25.1% (95% CI, 18.5-24.9; US mean, 3.8%), cesarean section, 62.6% (95% CI, 57.6-67.3; US mean, 31.9%), gestational diabetes, 5.7% (95% CI, 3.7-8.9; US mean, 9.2%), and pregnancy induced hypertension, 24.1% (95% CI, 18.1-31.5).

The rate of preterm birth (defined as babies born alive prior to 37 weeks of gestation) in the overall cohort was 43.1% (95% CI, 38.7-47.6) and the rate of neonatal mortality was 3.8% (95% CI, 2.8-5.2). The highest rates of preterm birth were in South America (55.0%) and the lowest were in North America (35.4%). Mean gestational age for newborns was 34.9 weeks (US mean, 38.7 weeks) and the mean birth weight was 2470 g (US mean, 3389 g). Compared with the US mean, neonatal mortality was high across all geographical regions; the highest rate was in Africa (18.4%) and the lowest was in North America (1.3%).

With the exception of neonatal mortality, results from the subgroup analyses for fetal outcomes were consistent with the present findings (the neonatal mortality rate was slightly lower in the subgroup analysis, 2.9% vs 3.8%).

Overall, the rate of acute graft rejection during pregnancy among 832 kidney transplant recipients was 9.4% (comparable to US mean of 9.1%). The highest rates of allograft failure were in Asia (11.0%); the lowest were in Africa (4.8%). Among 489 participants in 12 studies reporting 2-year post pregnancy graft loss, there were 52 cases of graft loss (9.2%).

The researchers cited the possibility of reporting bias, the inability to account for differences in socioeconomic and healthcare conditions, and the inability to assess pregnancy outcomes in relation to immunosuppression regimens as limitations to the findings.

“Although the outcome of live births is favorable, the risks of maternal and fetal complications are high in kidney transplant recipients and should be considered in patient counseling and clinical decision making,” the researchers said.
Kidney transplantation is the gold standard treatment for patients with end-stage renal disease (ESRD). The prevalence of mortality and major cardiovascular events in kidney transplant recipients has declined in recent years, and is lower among transplant recipients than in a matched chronic kidney disease (CKD) population. However, kidney transplant recipients continue to have an increased mortality and cardiovascular event risk compared with the general population, due in part to the conventional cardiovascular risk factors such as diabetes, hypertension, and renal dysfunction. There are also associations between transplant-specific factors such as immunosuppression medication, inflammation, and anemia and increased risk of cardiovascular events in kidney transplant recipients.

Stroke, while not as prevalent as other cardiovascular diseases, is a contributor to comorbidity and mortality in this patient population. However, there are few data on the epidemiology, risk pattern, and modification of stroke risk following renal transplantation. Researchers in Taiwan, led by Shih-Ting Huang, MD, recently conducted a retrospective study designed to estimate the absolute and relative risk of stroke among a large cohort of recent kidney transplant recipients in Taiwan. The study also sought to describe the predictors and mortality implications of stroke in kidney transplant recipients. Results were reported online in the International Journal of Environmental Research and Public Health [2019; doi:10.3390/ijerph16030326].

The study utilized data from the National Health Insurance Research Database in Taiwan from the years 2000 through 2010 to identify kidney transplant recipients (n=4635), patients with ESRD (n=69,297), and patients from the general population. However, there are few data on the epidemiology, risk pattern, and modification of stroke risk following renal transplantation. Researchers in Taiwan, led by Shih-Ting Huang, MD, recently conducted a retrospective study designed to estimate the absolute and relative risk of stroke among a large cohort of recent kidney transplant recipients in Taiwan. The study also sought to describe the predictors and mortality implications of stroke in kidney transplant recipients. Results were reported online in the International Journal of Environmental Research and Public Health [2019; doi:10.3390/ijerph16030326].

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The researchers divided the kidney transplant recipients into two groups: those who experienced stroke and those who did not to compare their characteristics. Of the kidney transplant recipients with stroke, 91.8% had hypertension, 37.3% had hyperlipidemia, and 32.9% reported underlying coronary artery disease. There was a significant increase in the risk of stroke with age (adjusted odds ratio [aOR], 1.02; 95% CI, 1.01-1.04 for each year of age) and the presence of diabetes (aOR, 2.08; 95% CI, 1.42-3.03) among the kidney transplant recipient patients.

Limitations cited by the authors included the retrospective design of the study and unpredictable confounding factors that may have influenced the outcomes; relying on administrative data regarding smoking, donor characteristics, and other transplantation factors; and the patients being predominantly Asian, possibly limiting the generalizability of the findings to other ethnic populations.

In conclusion, the researchers said, “We discovered that the risk for all types of stroke was lower among kidney transplant recipients than patients with ESRD, and was approximate to that of the general population. We also concluded that stroke was relatively uncommon after kidney transplantation, but it predicted an increased risk for death in kidney transplant recipients. We believe that vigilance in detecting and controlling modifiable cardiovascular event risk factors may be critical for reducing the risk of stroke and eventual death among kidney transplant recipients.”
WavelinQ™ 4F EndoAVF System Receives 510(k) Clearance from FDA

In February, BD (Becton, Dickinson and Company), a global medical technology company, received 510(k) clearance from the US Food and Drug Administration for the BD WavelinQ™ 4 French (4F) endoAVF system. The system is a recent innovation in endovascular arteriovenous fistula (endoAVF) creation technology; it allows for the creation of an AVF in either the ulnar artery and ulnar vein or the radial artery and radial vein and expands on the current indication for the BD WavelinQ™ 65F endoAVF system.

According to a press release, the BD WavelinQ 4F endoAVF system “provides clinicians with a minimally invasive AVF creation alternative to open surgery.” The system increases the anatomical AVF location options and enables additional venous wrist access points, creating procedural flexibility for physicians and reducing the risk of scarring or arm disfigurement for patients compared with open surgical AVF creation.

Paul Kreienberg, MD, Albany Medical Center, said, “With BD WavelinQ 4F endoAVF system, I can provide my ESRD patients with two additional fistula location options compared to a surgical fistula. These additional AV fistula sites and a minimally invasive procedure can increase the likelihood that patients will get a usable AV fistula.”

Steve Williamson, worldwide president of peripheral intervention at BD, said, “People living with ESRD are an underserved patient population with very limited treatment options available to them. We’re excited to add BD WavelinQ 4F endoAVF system to our portfolio of technologies that create, restore, and/or maintain AV access for patients on hemodialysis. Endovascular specialists now have an additional tool that enables the flexibility needed to support AV fistula creation for their patients.”

Prediction Tool Identifies Risk for Recurrent Kidney Stone Formation

Researchers from the Mayo Clinic in Rochester, Minnesota, recently described a new tool that can be used to predict which patients with recurring kidney stones are at the highest risk of remission. According to an article in Medical News Today, the Mayo researchers utilized 1984-2017 data from the Rochester Epidemiology Project that focused on chronic kidney stone formers from Olmsted County, Minnesota, representing 3364 patients with a total of 4951 stone-forming episodes.

With the identification of individuals most likely to experience repeat kidney stones, some patterns emerged; repeat stone formers tended to be male and younger and have higher body mass index. A family history of kidney stones and previous pregnancies are also risk factors for forming repeat stones.

An earlier tool that used 11 factors to predict the risk of repeat stone forming did not perform well on patients who had previously experienced ≥2 occurrences. The updated tool uses 13 independent predictors, including questions about sex, kidney stone history, and race, that extend the tool’s use and increase its prediction accuracy.

Satellite Healthcare Announces Majority Ownership of Tri-County Vascular Care

Satellite Healthcare, a not-for-profit dialysis provider in San Jose, California, has announced its purchase of a majority ownership of Tri-County Vascular Care, a freestanding vascular access surgery center. The purchase will allow Satellite Healthcare to provide dialysis patients in the South Bay area with vascular access surgical services. Satellite will assume leadership of the center in partnership with other area physicians. The combined expertise of Satellite Healthcare and Tri-County Vascular Care will create a resource to fulfill patients’ needs for optimal dialysis access, including fistulas, grafts, and peritoneal dialysis catheters.

In a press release, Rick Barnett, president and CEO of Satellite Healthcare, said, “Purchasing Tri-County Vascular Care offers access to a consistent team of medical professionals in a comfortable and friendly environment where the care of dialysis patients is a top priority. Vascular access staff are highly trained and can offer expedient service and focused attention.”

American Kidney Fund Names Research Fellows

The American Kidney Fund’s (AKF) Clinical Scientist in Nephrology Program is marking its 30th year in 2019. In a press release, the Fund announced the appointment of two research fellowships: Olivia Alison Potok, MD, a research fellow in nephrology at the University of California, San Diego, and Pablo Garcia, MD, a research fellow at Stanford University.

Through the AKF, the program funds researchers whose work aims to improve the diagnosis, treatments, and outcomes for patients with chronic kidney disease. Both of the newly announced fellowships will begin in July.

LaVarne A. Burton, president and CEO of AKF, said, “The research that Dr. Potok and Dr. Garcia will conduct promises to produce important insights with practical applications in the clinical setting. Over the past 30 years, the American Kidney Fund has granted research fellowships to 43 brilliant young nephrologists with one overarching goal: improving the care and treatment of patients with kidney disease. These nephrologists have, in turn, gone on to become leaders in the field and mentors to new generations of scientists studying kidney disease.

Dr. Potok’s research, funded with support from Akebia Therapeutics, Inc., will focus on improving understanding how two common markers used to estimate kidney function relate to aging and body composition. Dr. Garcia will work to clarify the causes and prognosis of primary tubulointerstitial kidney disease, a disorder in which the spaces between the kidney tubules become inflamed for unclear reasons.”
US Launch of 2008T BlueStar™ Hemodialysis Machine Announced

The market availability of the 2008T BlueStar™ hemodialysis machine has been announced by Fresenius Medical Care North America’s Renal Therapies Group. The machine incorporates evolved technologies and improved performance with more than 30 unique enhancements, representing the most comprehensive upgrade in company history, according to a press release from Fresenius.

The 2008T BlueStar machine is designed to provide simpler operation and maintenance with enhanced user control; the desired results include labor and cost savings, improved accuracy, enhanced data stream, and additional treatment options.

Mark Costanzo, president of the Renal Therapies Group at Fresenius Medical Care North America, said, “The new and enhanced 2008T BlueStar hemodialysis machines provide more than 30 unique enhancements to better serve end-stage renal disease patients undergoing dialysis. Our new machines represent a significant step forward for providers and patients who depend upon our life-sustaining technologies, and an exciting continuation of our 30-year commitment to the treatment of end-stage renal disease.”

Enhancements of the upgraded machine include auto start, auto prime, assisted refusion, idle mode, independent conductivity and pH self-test, disinfection log, Patient-Cards (optional), low volume therapy, sustained low efficiency dialysis, and enhanced Crit-Line® treatment data.

“Leveraging our history of innovation and industry firsts in renal care, we are pleased to unveil new features that will help providers deliver the highest quality of care to patients receiving hemodialysis both in-center and in the acute care setting,” Robert Kossmann, MD, chief medical officer at Renal Therapies Group at Fresenius Medical Care North America, said. “We believe our 2008T BlueStar machine offers distinct clinical advantages that streamline the complexities of hemodialysis care and enhance patients’ overall treatment experience.”

All enhancements are available for existing 2008T hemodialysis machines through an upgrade process.

Ellipsys® Vascular Access System Cleared for Use at VA Hospital

The US FDA recently cleared the Ellipsys® Vascular Access System for use in the creation of a percutaneous arteriovenous fistula (AVF), a less invasive innovation for patients with end-stage renal disease (ESRD). According to a recent press release, Mark Randel, MD, recently performed the new procedure at the Jack C. Montgomery Veterans Affairs (VA) Medical Center. The facility is the first VA center to offer the Ellipsys System.

In an interview published in Vantage Point, the official blog of the US Department of Veterans Affairs, Dr. Randel said, “This is a very innovative way of creating vascular access. It’s a game changer, and it transforms a commonly performed traditional surgery into a minimally invasive procedure that will benefit the veterans we serve.”

The system, developed by Avenu Medical in San Jose, uses an endoscopic approach to create the dialysis access. In the procedure, the Ellipsys catheter is advanced through the skin and into a vein, under ultrasound, to create access, leaving the tissue undisturbed.

According to the press release, Avenu has received a US Federal Contractors Service Agreement giving the company the ability to provide the Ellipsys technology to VA facilities nationwide. Ed Chang, co-founder and vice president of marketing at Avenu, said, “We are incredibly proud that the heroes of our nation, our military veterans, are among the first to receive this state-of-the-art treatment so they can get the care they need and deserve. Although ESRD is a global problem, the prevalence rate of ESRD among veterans is significantly higher than the general population. Therefore, working with the VA, we can directly address this pressing clinical need and take major steps toward fulfilling a treatment gap.”

Fresenius Medical Care Completes Acquisition of NxStage Medical

Following approval by US antitrust authorities, Fresenius Medical Care has successfully completed the acquisition of NxStage Medical, Inc. Fresenius Medical Care is the world’s largest provider of dialysis products and services; NxStage Medical develops, produces, and markets medical devices used in home dialysis and critical care.

In a press release, Rice Powell, chief executive officer of Fresenius Medical Care, said, “The closing of this transaction is an important milestone in enhancing our patients’ choice of dialysis treatment modality. By combining NxStage’s capabilities with our broad product and service offering, we can help patients to live even more independently. In addition to broadening our product portfolio, this acquisition positions Fresenius Medical Care to benefit from the growing trend toward home-based therapies.”

Bill Valen, Fresenius chief executive officer, added, “It’s a great pleasure to welcome our new NxStage colleagues. With their strong culture of innovation and transformation, they will help us to realize our vision of delivering access to superior patient care and outcomes in a lower-cost-of-care home setting for all the patients we care for. We are excited to execute on a strategy that is good for patients, the healthcare system, and us.”

TeleHealth Services Installs 3000th AV and Entertainment System

In a recent press release, TeleHealth Services announced the completion of its 3000th installation of audiovisual and entertainment systems to serve dialysis centers and patients. TeleHealth systems are in dialysis centers in each of the 50 states, including four of the top five clinical treatment providers, according to the press release. TeleHealth also offers advanced patient engagement and education solutions using patient room televisions and tablets for patients and staff.

Dan Nathan, executive vice president of operations for TeleHealth, said, “For patients in clinics and hospitals, the television offers a distraction during a challenging time. Quality television programming presents clinics and hospitals with a unique opportunity to engage and entertain patients. We work with our dialysis center customers to provide patient entertainment and AV services that improve convenience and satisfaction for patients receiving dialysis treatment, including the latest television equipment and familiar TV programming options.

“Patients appreciate entertainment options and amenities that offer the comforts they have at home. We are committed to providing innovative, turnkey technology solutions that help our hospital and clinic partners provide an exceptional patient experience.”
Abstract Roundup

**CHRONIC KIDNEY DISEASE**

**Possible Beneficial Effect of Statin Therapy on Iron Metabolism in Patients with CKD**

Anna Masajtis-Zagajewska, MD, PhD, and colleagues conducted a double-blind, randomized crossover study designed to examine the effect of 6-month administration of atorvastatin on hepcidin and hemojuvelin levels, inflammatory parameters, and iron metabolism in patients with chronic kidney disease (CKD) stages 3 and 4. The study cohort included 36 statin- and erythropoiesis-stimulating agent-naïve patients with low density lipoprotein cholesterol ≥100 mg/dL; study participants received atorvastatin or placebo for two 6-month periods.

In the course of the statin therapy, hepcidin decreased from 102 to 63 pg/mL (P < .001), but remained unchanged after placebo administration. There was no change in hemojuvelin after either part of the study. Following statin therapy, both interleukin-6 (IL-6) and high sensitivity C-reactive protein (hsCRP) decreased (from 8.7 to 8.1 pg/mL and from 4.7 to 4.0 mg/L, P=.4, respectively); there was no change in IL-6 or hsCRP after placebo administration.

There was a slight but significant increase in blood hemoglobin after 6 months of statin therapy; blood hemoglobin was unchanged after placebo administration. There was significant increase in total iron binding capacity and unsaturated iron binding capacity after 6-month statin therapy, as well as a tendency for an increase in serum iron. There was no difference in change in estimated glomerular filtration rate between the two study periods.

The researchers said, “Statins may have a small but potentially beneficial effect on serum hepcidin, which may lead to improvement of anemia control in CKD patients.”

**Efficacy of Bariatric Surgery Patients with CKD Varies with Stage**

Obesity Surgery. doi:10.1007/s11695-019-03703-z

Obesity is a known risk factor for chronic kidney disease and a relative contraindication for kidney transplantation; bariatric surgery is an option to address this issue. Boris Hansel, MD, and colleagues, hypothesized that there is an association between severe CKD and loss of efficacy of bariatric surgery, offering possible justification for recommendation of bariatric surgery at an earlier stage of CKD.

The researchers conducted a retrospective study of 101 patients to compare differences in weight loss at 6 and 12 months. Patients were stratified according to estimated glomerular filtration rate (eGFR): <30 including patients on dialysis; 30 to 59, 60 to 90, and ≥90 mL/min/1.73 m². Multivariate analyses were adjusted for sex, age, body mass index, surgical procedure, and diabetes. The researchers utilized a second method to confirm their hypothesis comparing weight loss in patients with stage 4 or 5 CKD, defined as eGFR <30 mL/min/1.73 m² (n=17), and matched controls with eGFR ≥90 mL/min/1.73 m².

In the first comparison, there was a positive association between eGFR and weight loss in the multivariate analysis. However, following exclusion of the subgroup of patients with eGFR <30 mL/min/1.73 m², the difference between the groups was no longer significant.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATION:** AURYXIA® (ferric citrate) is contraindicated in patients with iron overload syndromes.

**WARNINGS AND PRECAUTIONS:**

- **Iron Overload:** Monitor ferritin and transferrin saturation (TSAT). Patients may require a reduction in dose or discontinuation of concomitant intravenous (IV) iron.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients to keep AURYXIA out of the reach of children.

**PREGNANCY AND LACTATION:** Overdosing of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Rat studies have shown the transfer of iron into the fetus. Overdosing of iron in lactating women may adversely affect the nursing infant.

**ADVERSE REACTIONS:** The most common adverse reactions reported with AURYXIA in clinical trials were:

- **Iron Deficiency Anemia in CKD Not on Dialysis:** Disclosed feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%)

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799.

**FOR MORE INFORMATION, VISIT AURYXIA.COM**
The percent of total weight loss was significantly lower in patients with severe CKD compared with controls (−15% vs −23% at 6 months; \( P < .01 \); −17% vs −27% at 12 months; \( P < .01 \)). At 1 year, the percent of weight loss reached 47% in patients with stage 4 to 5 CKD and 68% in control subjects \( (P < .01) \). In the group with advanced CKD, surgery was a success (weight loss >50% of excess weight) in 38%, compared with 88% of controls \( (P < .01) \).

In conclusion, the authors said, “The efficacy of bariatric surgery was reduced in patients with advanced CKD. These results suggest early bariatric surgery in patients with early-to-moderate CKD.”

FOR MORE INFORMATION, VISIT AURYXIA.COM

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799

ADVERSE REACTIONS: The most common adverse reactions reported with AURYXIA in clinical trials were:

- Nausea
- Abdominal pain
- Headache
- Hyperkalemia
- Anemia
- Constipation
- Diarrhea
- Discoloration of stool
- Hematemesis
- Urticaria
- Rash

ADDITIONAL IMPORTANT SAFETY INFORMATION

Iron Deficiency Anemia in CKD Not on Dialysis: Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%).

Monitor ferritin and transferrin saturation (TSAT). Patients may require a reduction in the dose or discontinuation of concomitant intravenous (IV) iron if TSAT levels reach an abnormal range.

WARNINGS AND PRECAUTIONS:

- The use of AURYXIA in CKD not on dialysis is associated with nocturnal hyperkalemia.
- Ingestion of iron in pregnancy may have serious consequences.
- Iron overload may occur when AURYXIA is taken by a nursing woman or her infant.
- AURYXIA is contraindicated in patients with iron overload syndromes.
- Overdosing of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation.
- Rat studies have shown the transfer of iron into the fetus.
and validation (n=40,142) samples. A prediction model for three outcome categories (withdrawal, non-withdrawal death, survival at 6 months) as a function of demographics, morbidity, and functional status was created using multinomial logistic regression. Mean age of the training sample was 71.7 years, 44.9% were female, 72.9% were white, and 22.8% were black. At 6 months, 19.1% had died: 2022 (2.6%) withdrew and 15,223 (16.5%) died of a cause not related to non-withdrawal death; 1853 (7.7%) of all deaths were withdrawals. Baseline characteristics and event rates were similar among those in the validation sample. The model was adequately calibrated and could discriminate moderately well between withdrawal and survival (area under the ROC curve [AUC]: 0.77) and between non-withdrawal death and survival (AUC: 0.73). However, discrimination between withdrawal and non-withdrawal death was relatively low (AUC: 0.62). There were associations between older age and white, compared with non-white, race and greater odds of death; those associations were stronger for withdrawal than for non-withdrawal death. However, it is difficult to differentiate between patients who will experience early withdrawal versus non-withdrawal death, as many factors are similarly associated with both outcomes."
demographic, clinical, and lifestyle shifts in the population and improvements in renal replacement therapy. Planning for ESRD resource allocation should allow for substantial continued growth in the population of patients with ESRD. Future interventions should be directed to preventing the progression of CKD to kidney failure,” the researchers said.

**FABRY DISEASE**

**Prevalence of Fabry Disease in Transplant Recipients**

Nephron. doi.org/10.1159/000496620

Fabry disease, an X-linked lysosomal storage disorder, results from a lack of alpha-galactosidase A (AGALA) activity in lysosomes. Serkan Feyyaz Yalin, MD, and colleagues conducted a multicenter study designed to evaluate the prevalence of Fabry disease in renal transplant recipients in Turkey. Dialysis patients were used as a control group. The researchers measured AGALA activity in all male patients. Mutation analysis was conducted in male patients with decreased AGALA activity and in female patients as the initial diagnostic assay. A total of 5657 patients were screened; 17 mutations were identified. There was no significant difference seen between the groups regarding the prevalence of patients with mutation. Fabry disease was found even in patients with presumed primary kidney disease. Seventy-one relatives were analyzed and mutation was detected in 43. The screening also detected a patient with a new, unknown mutation (p.Cys223) in the GLA gene.

“These are important implications of the screening. First, detection of the undiagnosed patients leads to starting appropriate therapies for these patients. Second, the transmission of the disease to future generations may be prevented by prenatal screening after appropriate genetic counseling. In conclusion, we suggest screening of kidney transplant candidates for Fabry disease, regardless of etiologies of chronic kidney disease,” the researchers said.

**IGA NEPHROPATHY**

**Reduction in Proteinuria as a Surrogate End Point in IgA Nephropathy Trials**

Clinical Journal of the American Society of Nephrology. doi.org/10.2215/CJN.08802019

There are no approved therapies for the treatment of IgA nephropathy (IgAN), an important cause of end-stage renal disease (ESRD). Aliza Thompson, MD, MS, and colleagues recently conducted a Kidney Health Initiative designed to identify surrogate end points that could serve as reliable predictors of the effect of treatments on long-term kidney outcomes in IgAN and ultimately be used as a basis for approval. Proteinuria was identified as the most widely recognized and well-studied risk factor for progression to ESRD in patients with IgAN. Epidemiologic data show a strong and consistent relationship between the level and duration of proteinuria and loss of kidney function.

In trial-level analyses of data from 13 controlled trials, there was also an association between treatment effects of percent reduction of proteinuria and treatment effects on a composite of time to doubling of serum creatinine, ESRD, or death. The researchers said, “We conclude that data support the use of proteinuria reduction as a reasonably likely surrogate end point for a treatment’s effect on progression to ESRD in IgAN. In the United States, reasonable likely surrogate end points can be used as a basis for accelerated approval of therapies intended to treat serious or life-threatening conditions, such as IgAN. The clinical benefit of products approved under this program would need to be verified in a postmarketing confirmatory trial.”

**Fructose and Endotoxemia in Transplant Recipients**

Transplantation.2019;103(1):191-201

According to Winnie Chan, PhD, and colleagues, “The concepts that obesity is merely a consequence of overeating and that metabolic health then reflects obesity may be insufficient and potentially flawed.” There is increased attention being paid to the role of fructose intake and metabolic endotoxemia; however, there are few data in kidney transplantation recipients. The study enrolled 128 kidney transplant recipients who were 21 year post-transplant. Clinical, biochemical, anthropometric, and questionnaire assessments were completed. Obesity (defined as body mass index ≥30 kg/m²) was found in 36.7% of the cohort and metabolic syndrome in 50%.

There were independent associations between increased intake of fructose and metabolic syndrome and between increased endotoxin level and metabolic syndrome (P<.01 and P=.02, respectively). Increased intake of fructose was associated with the central obesity (P=.01) and with hyperglycemia (P<.001) criteria of metabolic syndrome. Higher endotoxin level was associated with hypertriglyceridemia (P=.003) and low concentration of high-density lipoprotein cholesterol (P=.002) criteria.

There was no independent association between saturated fat or total caloric intake and obesity and metabolic syndrome; nor was there an independent association between obesity or central obesity with the dyslipidemia and hyperglycemia criteria of metabolic syndrome.

In conclusion, the researchers said, “Dietary modification through decreasing fructose intake and addressing systemic endotoxemia are plausible targets for improving the metabolic health of kidney transplant recipients.”

**Proteinuria**

Surrogate End Point in IgA Nephropathy

doi.org/10.1681/ASN.2018070726

In trial-level analyses of data from 13 controlled trials, there was also an association between treatment effects of percent reduction of proteinuria and treatment effects on a composite of time to doubling of serum creatinine, ESRD, or death. The researchers said, “We conclude that data support the use of proteinuria reduction as a reasonably likely surrogate end point for a treatment’s effect on progression to ESRD in IgAN. In the United States, reasonable likely surrogate end points can be used as a basis for accelerated approval of therapies intended to treat serious or life-threatening conditions, such as IgAN. The clinical benefit of products approved under this program would need to be verified in a postmarketing confirmatory trial.”

**Transplantation**

Changes In Cognitive Function among Frail Transplant Recipients

Journal of the American Society of Nephrology. doi.org/10.1681 ASN.2018070726

Post-transplant restoration of kidney function generally improves cognitive function; however, there are few data on whether frail recipients, who are more susceptible to surgical stressors, achieve improvements in cognitive function following kidney transplantation or whether they experience a subsequent decline in cognitive function as they age with a functioning graft.

Nadia M. Chu, PhD, MPH, and colleagues recently conducted a two-center cohort study designed to examine pretransplant frailty (Fried physical frailty phenotype) and cognitive function (measured by the Modified Mini-Mental State Examination) in adult kidney transplant recipients. The researchers measured cognitive function up to 4 years post-transplant and characterized cognitive trajectories by pre-transplant frailty (Fried physical frailty phenotype) and cognitive function (measured by the Modified Mini-Mental State Examination) in adult kidney transplant recipients. The researchers measured cognitive function among frail transplant recipients who were ≥1 year post-transplant.

A total of 665 transplant recipients were followed for a median of 1.5 years. Mean age was 52.0 years and 15.0% were frail. Follow-up visit data were available for frail recipients (89.0 vs 90.8 points). Following adjustment, pretransplant cognitive scores to prevent cognitive decline among frail recipients should be identified,” the researchers concluded.
New Frequency of Hemodialysis
Local Coverage Determinations

Effective March 1, 2019, several Medicare Administrative Contractors (MACs) began processing claims for hemodialysis treatments under new Local Coverage Determinations (LCDs). These LCDs underwent massive revisions after the proposed LCDs released in 2017 would have essentially eliminated reimbursement for more than three treatments per week because they were so strict. Medicare, the largest payer in the United States dialysis industry, provides benefits and has built the current payment structure for dialysis around the three hemodialysis treatments per week model. There are a variety of scenarios where more frequent hemodialysis treatments are necessary for patients. Medicare has delegated the responsibility of determining the medical necessity of any treatments in excess of three per week to the Medicare Administrative Contractor.

Historically, there has been a fair amount of variation in the coverage policies held by each MAC for frequency of hemodialysis. Some MACs accepted six or seven different diagnoses as justification for additional dialysis sessions and the ICD-10 codes were published in their online policy, whereas other MACs had private lists of diagnoses that were not available for public viewing.

In late 2017, several MACs released identical draft LCDs regarding the frequency of hemodialysis that could have eliminated reimbursement for more than three treatments per week in all but the most extreme cases. Many groups with a stake in the renal community submitted comments to the MACs and the Secretary of Health and Human Services calling for changes to the final policy to allow reimbursement for all medically necessary additional treatments, not just those treatments related to acute conditions or acute onset.

Subsequently, all the MACs participated in a Contractor Advisory Committee meeting in which they reviewed the comments received by each contractor and incorporated some of the requested changes into their final LCDs. The resulting final LCDs contain 53 diagnoses ranging from “Disorder of phosphorus metabolism, unspecified” to “Other specified complication of vascular prosthetic devices.” The LCDs are clear that coverage for additional sessions is available if conditions such as medical necessity, documentation that meets specific documentation guidelines, and appropriate use of billing modifiers are met. The documentation sources acceptable for supporting medical necessity have been expanded in the new LCD to include documents from recent hospital care, office visits, dialysis progress notes, or the nephrologist’s monthly capitation payment (MCP) visit notes. Additionally, the MACs released accompanying Hemodialysis Coding Guideline local coverage articles (LCAs) that define the billing and coding expectations that should be followed by dialysis billers. The new policies include a statement indicating the MACs will be monitoring the frequency of additional sessions and this may trigger a Medical Review or the addition of new diagnoses to the list of covered conditions.

What is Not Covered?
Three scenarios are given by the MACs to describe additional dialysis sessions that would not be covered.

- Treatments not fully supported in the patient’s medical record
- Planned inadequate or short dialysis
- Treatments performed for convenience of patient or staff

Key Difference in the MACs’ LCDs
While preparing training materials for our staff on the new LCDs, I compared all the LCDs and LCAs side by side. For the most part, there are only a few minor differences in wording that have little impact on the meaning of the policies. The LCAs for CGS, Palmetto, First Coast Service Options, Novitas, NGS, and Noridian contain three approaches of billing:

1. The standard three treatments per week
2. For dialysis sessions considered not to meet the medical justification for payment
3. Medically justified dialysis sessions outside routine dialysis orders; to be used for medical conditions that may justify payments on an acute or short-term basis.

The hemodialysis coding guidelines released by WPS contain these same three approaches, but they include a fourth approach:

4. Medically appropriate and necessary dialysis exceeding 14 treatments per month and outlined in the Dialysis Orders. Some patients, due to chronic or long-term conditions, may require dialysis that exceeds the usually covered 14 treatments per month (three treatments per week).

I applaud WPS for this small addition to their coding guidelines and I hope the other contractors amend their LCAs to include the fourth approach in their LCAs as well.

Contractor Name | Jurisdiction | LCD ID | LCA ID |
---|---|---|---|
Wisconsin Physicians Service Insurance Corporation (WPS) | JS, JB | L37537 | A55703 |
CGS Administrators | JS | L37575 | A56159 |
Palmetto GBA | JG, JM | L34575 | A55354 |
First Coast Service Options | JN | L37564 | A56262 |
Novitas Solutions, Inc. | JH, JL | L35014 | A55723 |
National Government Services, Inc. (NGS) | JG, JK | L37475 | A55672 |
Noridian Healthcare Solutions, LLC | JF, JE | L37504, L37502 | A55676, A55675 |

Sarah Tolson is the director of operations for Sceptre Management Solutions, Inc., a company specializing in billing for outpatient ESRD facilities, nephrology practices, and vascular access. Your questions are welcome and she can be reached at stolson@sceptremanagement.com, 801.775.8010, or via Sceptre’s website, www.sceptremanagement.com.
Study Examines First and Second Fistula Catheter-Free Use

Worldwide, more than 2 million people with chronic kidney failure receive treatment via hemodialysis therapy. Reliable access to the bloodstream is achieved using an arteriovenous fistula, an arteriovenous graft, or a central venous catheter. The most common forms of access in Canada are fistulas and catheters; grafts are used in <5% of patients. Relative to use of a graft or catheter, fistulas are associated with lower mortality and infection rates; catheter use is associated with a higher risk for adverse events. Initiatives have been implemented in Canada to increase fistula use, and worldwide guidelines have adopted a fistula-first/catheter-last paradigm.

The risk for primary fistula failure due to early clotting following surgical creation or failure of the fistula to mature are barriers to increasing fistula use. Primary failure occurs in approximately one in four created fistulas, and, despite interventions to restore patency, one in five fistulas is nonfunctional at 1 year. Results of previous studies have not provided clear evidence-based criteria to identify people who, based on clinical characteristics, would most benefit from fistula creation. In those studies, definitions of fistula maturation were based on achieved hemodialysis blood flow rates on fistula cannulation. According to Fareed Kamar, MD, and colleagues, “These definitions do not discern whether a fistula has become sufficiently reliable to allow catheter scheduling versus Emergency-Only Dialysis in Undocumented Immigrants

Despite nearly universal coverage for scheduled dialysis in the United States via Medicare and Medicaid, in 40 of 50 states, undocumented immigrants receive emergency-only dialysis, defined as intermittent and provided in emergency departments (EDs) when patients present with imminently life-threatening indications including severe metabolic acidosis, hyperkalemia with impending fatal arrhythmia, uremia with altered sensorium, or severe volume overload with hypoxia. As mandated under the 1986 Emergency Medical Treatment and Labor Act, patients receive enough dialysis to alleviate the life-threatening indications; they are instructed to return when symptoms indicating the need for dialysis arise again.

AKI Following Contrast-Enhanced Computed Tomography in Pediatric Patients

Contrast-induced nephropathy (CIN) is the development of acute kidney injury (AKI) following exposure to iodinated contrast material, with incidence of AKI following intravenous contrast administration estimated to range from 1% to 20%, depending on the definition of AKI and the patient cohort. Compared with patients who do not develop CIN, those that do experience a higher rate of need for renal replacement therapy and death. Patients identified as at risk for CIN may have contrast-enhanced examinations and procedures delayed or avoided. However, according to Jennifer S. McDonald, PhD, and colleagues, severity of CIN may have been overestimated in previous studies due to the lack of control groups of patients not administered contrast, and the attribution of all cases of postcontrast AKI in the contrast-exposed group in those studies to CIN rather than other potential causes of AKI.

Further, there are few data available on the risks of administration of iodinated

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Rx Only. For the safe and proper use of the devices mentioned herein, please refer to the appropriate Operator’s Manual.

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“The ability to look at the trends in our data has made a huge change in the way we provide therapy. The reporting with TRUEVUE Analytics has allowed us to really improve our goals and communication.”

— Jillian, RN

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