Associated Costs Lower for Endovascular AVF Creation

Arteriovenous fistula (AVF) is the preferred access type, offering longer access survival, lower risk of mortality, and reductions in rate of infection. AVF also requires fewer interventions following successful maturation and use.

Recent studies have suggested that maturation and maintenance of function may require two or more additional procedures following the initial AVF creation. Additional procedures notwithstanding, a proportion of AVFs do not become usable for hemodialysis, requiring patients to rely on temporary central venous catheters prior to creation of a functional AVF.

An alternative to the traditional open surgical approach for AVF creation, a new endovascular catheter-based system (the everlinQ endoAVF System) has been developed that uses a minimally invasive method to create an endoAVF. The system creates a side-to-side anastomosis without open surgery or dissection of vessel. The NEAT (Novel Endovascular Access Trial) was conducted to assess the efficacy and safety of endoAVF creation in patients with stage 4 chronic kidney disease (CKD) requiring vascular access for hemodialysis.

Marc Glickman, MD, and colleagues conducted a retrospective observational study designed to provide insight into the potential economic

Initial Dialysis Session Duration Associated with Patient Outcomes

Following expansion of Medicare coverage to patients with end-stage renal disease (ESRD) 40 years ago, the average number of hours per hemodialysis session has decreased from 6 hours in 1973 to 3.5 to 4 hours in 2010. The decline is explained in part by the improved efficiency of dialyzers; however, there are few data on the clinical consequences of shorter session duration on patients on maintenance hemodialysis.

Endovascular AVF May Be Viable Option for Vascular Access in Hemodialysis Patients

The recommended method of vascular access is the surgical creation of an arteriovenous fistula (AVF), a technique developed in 1966. At present, only 14% of patients with end-stage renal disease in the United States initiate hemodialysis with an AVF; in addition, prevalent use of AVFs is low in many regions worldwide.

Factors contributing to underuse of AVF include long cumulative waits for surgical consultation and creation of the AVF, a process that can take from 3 to 10 weeks to complete; convenient and time-consuming preoperative visits; patient refusal of surgery; surgical risk; and high early thrombosis of 12% to 26%. Further, maturation of the AVF can be challenging, requiring use of bridging catheters and an average of 1.5 to 3.3 procedures to allow fistula usability.

Using an endovascular approach to create an AVF may reduce vessel trauma and lessen the stimulus for intimal hyperplasia linked with failure of an AVF to mature. Morbidity may also be reduced, improving patient acceptance and

PCI versus Optimal Medical Management in Patients with Advanced Chronic Kidney Disease

There was no plausible risk for infection even with temporary catheters that would favor medical management over PCI first.

Home Telemonitoring of Patients with Chronic Kidney Disease

French researchers are conducting a pragmatic randomized controlled trial to compare home telemonitoring with usual care in three populations of CKD patients.

Focus on Transplantation: Cognitive Impairment among Kidney Transplant Recipients

Kidney transplant patients have several risk factors for cognitive impairment, including comorbid illness, depression, and reduced physical activity.

PLUS...

From the Field

New Bill Cuts Facility Certification Delays and Expands Telehealth Options
Help your new-to-dialysis patients succeed with Velphoro

Start with high potency. Stay with long-term control.∗1

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 must be administered with meals. Velphoro tablets must be chewed and not swallowed whole. To aid with chewing and swallowing, the tablets may be crushed.
• 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 (6%).
• 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 doxycycline at least 1 hour before Velphoro. Velphoro should not be prescribed with oral levothyroxine.

Please see Brief Summary on adjacent page or visit www.Velphoro.com for full Prescribing Information.

† A 52-week, open-label, active-controlled, phase 3 study evaluated the safety and efficacy of Velphoro in lowering serum phosphorus levels in patients (N=1,054) with chronic kidney disease on hemodialysis or peritoneal dialysis.1

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.

DOSAGE 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.

DOSAGE 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 hemochromatosis 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%).

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 doxycycline at least 1 hour before Velphoro.

Velphoro should not be prescribed with oral levethyroxine.

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
Store in the original package and 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 must be chewed and not swallowed whole. To aid with chewing and swallowing, the tablets may be crushed [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.

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Waltham, MA 02451

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Fractures in chronic kidney disease (CKD) patients, particularly those that are elderly, have substantial morbidity and mortality. The Kidney Disease Improving Global Outcomes 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (KDIGO CKD-MBD)\(^1\), published in July 2017, has provided an important update over the previous 2009 guidelines in one major area—osteoporosis and fracture risk.

For patients in CKD stages G3a (glomerular filtration rate [GFR] of 45-59 ml/min/1.73m\(^2\)) to G5D (patients on dialysis), the newly updated guideline 3.21 states, “We suggest BMD [bone mineral density] testing to assess fracture risk if results will impact treatment decisions [2B].” In the 2009 guideline [3.2.2], the KDIGO-MBD workgroup had recommended against routine BMD testing “because BMD does not predict fracture risk as it does in the general population, and BMD does not predict the type of renal osteodystrophy [2B].” The new update documents multiple new prospective studies and post hoc analyses from clinical trials. Furthermore, in the newly updated guideline, the KDIGO Work Group voted to remove the requirement of bone biopsy prior to the use of anti-resorptive therapy for osteoporosis.

Published data from 2009 onwards reveal three salient points:

1. Lower total hip and femoral neck BMD using dual-energy X-ray absorptiometry (DXA) predicts fractures in patients with CKD stage 3a to stage 5D patients.
2. Osteoporosis anti-resorptive medications have similar efficacy on improving BMD and reducing fracture incidence in patients with CKD stage 3a, compared with those with normal or near normal eGFR.
3. Evidence is lacking on whether DXA in children and adolescents predicts fractures.

Performing a DXA is pretty straightforward. The more challenging question is: what should one do for a low BMD?

The approach I plan to use is as follows:

1. Routinely perform DXA in patients with CKD Stage 3a-5D
2. Assess fracture risk with the Canadian WHO fracture risk assessment (FRAX\(^\circ\)) tool (https://www.sheffield.ac.uk/FRAX/tool.jsp). Fraser and colleagues\(^2\) report “FRAX with BMD showed better fracture discrimination than FRAX without BMD or BMD alone.”
3. In most CKD patients with a low or declining BMD, begin anti-resorptive therapy and monitor the patient with serial DXAs\(^2\). Of note, the 2017 Update does not require a bone biopsy before beginning anti-resorptive therapy.
4. Consider performing a bone biopsy in patients who have either not improved their BMD score despite therapy, have refractory hypercalcemia, or have sustained an unexpected fracture. The bone biopsy should be performed with the goal of demonstrating on quantitative bone histomorphometry low trabecular bone volume and disrupted microarchitecture.

REFERENCES
The number of deaths within 1 year of dialysis initiation was 5492 in the ≥4-hour group and 10,372 in the 3-hour group.

december 2012. The cohort included 39,172 patients from 852 facilities who initiated treatment for ≥4 hours and 47,721 patients from 631 facilities who initiated treatment for 3 hours. The primary outcomes of interest were 2- and 1-year mortality rates.

Patients treated at ≥4-hour facilities were approximately 3 years younger than those treated at 3-hour facilities. A larger proportion of patients treated at ≥4-hour facilities were black compared with patients treated at 3-hour facilities (39% vs 21%). The remainder of the individual-level characteristics were similar across the ≥4-hour and 3-hour facilities.

The primary facility-level differences between ≥4-hour and 3-hour centers were that the 3-hour facilities were eight percentage points less likely to accept transient patients, eight percentage points more likely to have evening dialysis sessions, 10 percentage points more likely to report isolation dialysis sessions, and 10 percentage points less likely to reuse dialyzers compared with ≥4-hour facilities. Zip codes for the locations of ≥4-hour facilities had a lower total number of patients compared with zip codes for locations of the 3-hour facilities (85 vs 71).

The number of deaths within 1 year of dialysis initiation was 5492 in the ≥4-hour group and 10,372 in the 3-hour group; at 2 years, the total number of deaths at the ≥4-hour group was 8945 compared with 15,624 deaths in the 3-hour group (85 vs 71).

The 1-year mortality rate for patients who initiated hemodialysis at ≥4-hour facilities was 15.2 per 100 person-years, compared with 25.0 per 100 person-years for those who initiated hemodialysis therapy at 3-hour facilities. The 2-year mortality rates were 13.1 per 100 person-years and 20.5 per 100-person-years, respectively.

In a proportional hazard model that adjusted only for the year of initiation, the 2-year hazard ratio (HR) of death among those treated at ≥4-hour facilities was 0.72 (95% confidence interval [CI], 0.66-0.78). Following adjustment for individual demographic and clinical characteristics, the HR was 0.78 (95% CI, 0.71-0.85). In a model that used inverse probability weights to re-weight the data, the HR was 0.79 (95% CI, 0.73-0.86). HRs for 1-year mortality were 0.70 (95% CI, 0.64-0.76), 0.76 (95% CI, 0.69-0.83), and 0.77 (95% CI, 0.70-0.84), respectively.

Estimates of HRs and 95% CIs stratified by age, sex, race, and presence or absence of heart disease and diabetes were similar to those in the primary analysis, suggesting a consistent association of ≥4-hour initial session duration with lower mortality compared with 3 hours of initial session duration.

Limitations cited by the authors included lack of observation of hemodialysis dosage in sessions subsequent to initiation and only including patients treated in facilities with uniform session length at initiation for all their patients. Further, there was no available information on dialysis dosage and patients’ residual kidney function at baseline.

In conclusion, the researchers said, “We conducted a nationally representative quasi-experimental study of hemodialysis outcomes in a select group of facilities that appear to assign the exact same initial treatment times to all their incident patients irrespective of clinical risk. We find that survival within 2 years is higher among patients who initiate hemodialysis therapy in facilities with ≥4 hours of hemodialysis relative to their counterparts who initiate hemodialysis in facilities that treat all incident patients for 3 hours. This analysis suggests that longer hemodialysis session length may improve outcomes, although further study is needed to establish the degree to which these findings generalize to facilities that prescribe varying hemodialysis session durations.”

TAKEAWAY POINTS

Researchers conducted a retrospective cohort study to compare mortality rates of patients with end-stage renal disease treated in dialysis facilities that used initial session durations of either ≥4 hours or 3 hours for all incident patients.

At 2 years following initiation of dialysis, there were 8945 deaths in the ≥4-hour group and 15,624 deaths in the 3-hour group. The 2-year mortality rate in the ≥4-hour group was 13.1/100 person-years versus 20.5/100 person-years in the 3-hour group.

The 2-year adjusted hazard ratio in the ≥4-hour group relative to the 1-hour group was 0.77 (95% confidence interval, 0.70-0.84).
TAKEAWAY POINTS

Researchers conducted a retrospective observational study to compare the rates and associated costs of procedures performed following creation of an arteriovenous fistula (AVF) with those following creation of an endovascular AVF (endoAVF).

The post-procedure event rate for patients in the surgical AVF (SAVF) cohort was $4.63 per patient-year, versus 0.59 per patient-year in the endoAVF cohort.

The average cost of post-creation procedures was US $13,033 for the SAVF cohort versus US $1794 for the endoAVF cohort.

Impact of endoAVF creation. The researchers compared the rates and associated costs of procedures performed following the initial AVF creation to facilitate or maintain AVF usability between patients with the endoAVF system (endoAVF cohort) and a propensity score-matched cohort of Medicare beneficiaries with a traditional surgical AVF (SAVF cohort). Results were reported in the Journal of Vascular Access [doi:10.5301/jva.5000723].

The study utilized data from the Centers for Medicare & Medicaid Services 5% Medicare Standard Analytical Files from 2010 to 2014 as well as clinical data from NEAT, a single-arm, prospective, multicenter study, included 60 evaluable patients who had an endoAVF created and were followed for one year.

The 60 patients in NEAT comprised the endoAVF cohort in the current study. They were matched in a 1:1 ratio to patients in the SAVF cohort. Comparisons of the two cohorts were made of event rates of procedures required post-creation to facilitate and maintain the AVFs, along with the associated costs.

Using 1:1 propensity score matching of baseline demographic and clinical characteristics, of 3764 adult Medicare SAVF patients, 60 were successfully matched to the 60 patients in the endoAVF cohort.

Following matching, baseline demographic and clinical characteristics were balanced between the two cohorts. Mean age was 61.1 years in the SAVF patients and 60.0 in the endoAVF patients; 37% of SAVF patients and 39% of endoAVF patients were male, and 36% of each cohort were white.

The total procedure rate for the matched SAVF cohort was 3.43 per patient-year, compared with 0.59 per patient-year for the endoAVF cohort (P<.05). Compared with SAVF, event rates per patient year for endoAVF were lower for angioplasty (0.93 vs 0.04), thrombectomy (0.20 vs 0.04), catheter placement (0.43 vs 0.11), arteriovenous graft creation (0.07 vs 0.02), new surgical creation of AVF (0.30 vs 0.11), and vascular-access-related infections (1.23 vs 0.02), all P<.05.

Average cost for post-creation procedures was US $13,033 for the SAVF cohort and US $1794 for the endoAVF cohort; costs for the endoAVF cohort were US $11,240 lower in the endoAVF cohort than in the SAVF cohort. In a secondary analysis using only Medicare patients whose index date event was direct arteriovenous anastomosis versus the endoAVF cohort, there were no statistically significant differences in results of the cost comparisons.

Because the mean follow-up time in the endoAVF cohort was longer than in the SAVF cohort (10.9 months vs 6 months), the researchers conducted a sensitivity analysis with data on endoAVF patients censored at 6 months. The sensitivity analysis demonstrated a total event rate of 3.43 per patient-year for the SAVF cohort compared with 0.78 per patient-year for the endoAVF cohort (P<.05). The cost comparisons revealed a savings in average procedure-related costs for the endoAVF cohort of US $10,533 per patient-year compared with the SAVF cohort.

The researchers cited some limitations to the study, including the use of Medicare data for the SAVF cohort patients; the presence of a procedure or diagnostic code on a medical claim does not guarantee the presence of the procedure or of the diagnosis unless they are validated against medical charts. Further, Medicare inpatient, outpatient, and Part B claims were used to estimate post-creation procedure-related costs, without inclusion of any pharmacy costs or costs related to diagnostic procedures. Finally, in the SAVF cohort, pre-dialysis status could not be determined; approximately half of the patients in the NEAT cohort were pre-dialysis and thus may have required fewer post-creation AVF procedures.

In conclusion, the researchers said, “The rates of post-creation procedures were found to be significantly lower in patients who had AVF created by an endovascular approach (endoAVF) compared with the traditional surgical approach. The associated average cost of procedures to attain and maintain the AVF in the first year following AVF creation was lower in the endoAVF cohort compared with the SAVF cohort. Longer follow-up of endoAVF clinical outcomes and their economic impact will be insightful and important for its wider adoption.”

Facilitating Transition of Care from Hospital Discharge to Outpatient Dialysis Unit

Orlando—The transition from hospital discharge to return to the dialysis unit is a vulnerable time for patients on maintenance hemodialysis. Unsafe transitions put patients at risk for adverse outcomes, visits to the emergency department (ED), and hospital readmission. At the University of Pennsylvania Hospital, 44% of dialysis patients discharged from the hospital had at least one ED visit within 30 days, and 29% of dialysis patients discharged from the hospital were readmitted within 30 days. “Tiffany C. Wong, MD, and colleagues at the University of Pennsylvania Hospital implemented a quality improvement project designed to make the transition of care safer for dialysis patients discharged; the program aimed to facilitate communication between the patients’ primary care physician and the renal consult team, using an automated discharge alert. Dr. Wong et al. reported on the project’s results during a poster session at the NKF Spring Clinical Meetings in a poster titled Improving the Transition of Care of Dialysis Patients Between Hospital Discharge and Return to the Dialysis Unit.

The researchers developed an automated discharge alert in cooperation with the Penn Medicine Center for Health Care Innovation; the alert was sent when the primary care team issued a discharge order for a dialysis patient. The renal fellow then had time to contact the primary care team with possible new recommendations, verify changes in medications, coordinate use of antibiotics, and contact the outpatient nephrologist. The dialysis social worker was also notified to send a discharge information packet to the dialysis center.

Following implementation of the automated discharge alert, sent as both an e-mail and a text page to the covering fellow and as an e-mail to the dialysis social worker, surveys of the receiving fellows demonstrated that 58.3% of respondents were not aware that their patient was being discharged. The alert resulted in 8.3% of survey respondents contacting the primary care team, 8.3% making a new recommendation to the primary care team, and 16.7% contacting the patient’s dialysis center.

The alert was modified to include additional information that included the name and contact information for the outpatient nephrologist and the name and contact information for the outpatient dialysis unit. In addition, feedback from the fellows resulted in eliminating the test page and using only e-mail to send the alert; further, the alert was also sent to the outpatient nephrologist. Finally, the automated discharge system was expanded to include Penn Presbyterian Medical Center.

‘By using a standardized quality improvement framework, we were able to improve the transition of care for dialysis patients between hospital discharge and return to the dialysis unit. Since development of this automated discharge alert system, our hospital system has switched to EPIC. Future efforts will be focused on developing a new automated discharge alert system within EPIC,’ the researchers said.

fistula use. Charmaine E. Lok, MD, MSc, and colleagues previously reported developmental work regarding a novel magnet-based endovascular technology to create an AVF (endovascular AVF [endoAVF]) at a single-center in a population of young patients with no significant vascular disease.

In the American Journal of Kidney Diseases [http://dx.doi.org/10.1053/j.ajkd.2017.03.026], the researchers reported on results of NEAT (Novel Endovascular Access Trial), an international prospective clinical study designed to assess the safety and efficacy of the technique with multiple operators and in a board population of patients with chronic kidney disease (CKD). The study cohort included consecutive adult non–diabetes-dependent and dialysis-dependent patients who were referred for creation of vascular access at nine centers in Canada, Australia, and New Zealand. The intervention of interest was use of catheter-based endovascular technology and radiofrequency energy to create an anastomosis between target vessels, resulting in an endoAVF. A total of 80 patients were enrolled from January 2014 to August 2015. Twelve-month study follow-up was completed by the last participant in August 2016. The current report included data on the 60 patients with full-analysis-set data. Of those 60, mean age at baseline was 59.9 years, 65% were men, 57% had non–diabetes-dependent CKD, and 42% had a central venous catheter in situ. Prior to end point evaluation, one patient died (cardiac causes unrelated to the procedure), and two participants had inadvertent endoAVF sacrifice related to brachial artery complications, yielding evaluable data for 57 participants used for evaluable cohort analysis. In 98% of cases (59/60), endoAVF creation was successful. In the one unsuccessful case, the investigator used a braided vascular sheath that acted as an energy sink and prevented adequate radiofrequency energy delivery to create the anastomosis.

In the full-analysis-set cohort, the primary efficacy end point (physiologic suitability of the endoAVF for dialysis) was met in 52 of 60 patients (87%; 95% confidence interval [CI], 75%-94%). In the evaluable cohort, the end point was met in 52 of 57 patients (91%; 95% CI, 81%-97%). Mean brachial artery flow increased from a baseline level of 82 mL/min to 918 mL/min at 3 months (P < .001). There was significant increase in all draining veins from baseline to 3 months (all P < .001). Mean change in vein diameter and mean vein diameters at 3 months (in parenthesis) were: median cubital vein: 1.7 (5.9) mm; cephalic vein: 2.0 (5.2) mm; and basilic vein: 1.8 (6.0) mm.

In patients in the full-analysis set who received dialysis, endoAVF functional usability was 64% (28/44; 95% CI, 48%-78%).

TAKEAWAY POINTS

- An endovascular approach to fistula creation without open surgery provides a minimally invasive option for vascular access for patients requiring hemodialysis.
- NEAT (Novel Endovascular Access Trial) is a prospective, single-arm multicenter study designed to assess the safety and efficacy of creating an arterovenous fistula (AVF) using an endovascular approach (endoAVF).
- Results of NEAT demonstrated that an endoAVF can be reliably created using a radiofrequency magnetic catheter-based system.

In patients who had completed the program, most (95%) expressed interest in offering patients and clinicians a minimally invasive option for AVF creation, as researchers reported.

In the full-analysis-set cohort had thrombosis within 3 months, and 11% within 12 months. Study limitations cited by the authors included the single-arm design of the study, and the lack of a surgical comparator.

“Endovascular autogenous fistula creation using a radiofrequency magnetic catheter-based system reliably produces fistulas that are physiologically mature and functionally usable for hemodialysis. Functional usability was achieved with few complications, offering patients and clinicians a minimally invasive option for AVF creation,” the researchers said.

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**Education Program Helps Patients Make Modality Decisions**

**Orlando**—In the United States, end-stage renal disease (ESRD) represents a burden to public health and increases pressure on healthcare costs. Data from 2014 identified approximately 680,000 prevalent cases of ESRD in the United States; up to 38% of incident patients did not receive care from a nephrologist prior to renal replacement therapy initiation.

Percentages of treatment modalities in the United States were hemo dialysis 87.9%, peritoneal dialysis 9.3%, and kidney transplantation 2.6%. In comparison, in New Zealand, the percentages were 55.6% hemodialysis, 39.8% peritoneal dialysis, and 4.6% transplantation; in Hong Kong, they were 83.1% peritoneal dialysis, 13.9% hemodialysis, and 3% transplantation.

Costs for treatment for ESRD per patient per year in US Medicare 2014 were $32,586 for transplantation, $73,612 for peritoneal dialysis, and $87,638 for hemodialysis. Currently, there is no standardized approach to patient education regarding options for ESRD treatment. Patients may make modality decisions too late to allow for selection of the best treatment, resulting in possible higher costs and higher morbidity at initiation of treatment. According to Anna Malkina, MD, and colleagues at Cricket Health Inc., lack of patient education results in missed opportunities to increase rates of home dialysis therapies and kidney transplantation among eligible patients.

Cricket Health has developed a technology-enabled program designed to educate patients with advanced chronic kidney disease (CKD) regarding options for treatment of ESRD. The program is conducted online and offers a supportive environment for patients to become familiar with the available options. The researchers designed a pilot prospective implementation program to assess the feasibility of offering the platform to patients. The pilot also aimed to evaluate patient choice of modality following completion of the program. Results to date were reported during a poster session at the NKF 2017 Spring Clinical Meetings in a poster titled Technology-Enabled Education on ESRD Treatment Options via Integrated Patient and Provider Online Community.

The pilot program included 27 patients with CKD stages 3b, 4, and 5 (estimated glomerular filtration rate <45 mL/min/1.73 m²) from four nephrology practices in California. Inclusion criteria were age >18 years, fluency in English, and access to an internet-connected personal computer or mobile device. Of the 27 patients, five are currently involved in the program; 19 have completed the program and have made a modality decision, and three have completed the program but have not made a modality decision. Average age of the patients is 62.5 years, 19 are male, seven accessed the program on a mobile device, and 20 utilized a laptop or desktop computer.

Of the 19 who have completed the program and made a modality decision, 15 chose peritoneal dialysis (79%), two chose home dialysis (10.5%), and two chose in-center hemodialysis (10.5%). The average number of days to making a decision was 33.6; the average number of videos watched was 8.3, the average number of frequently asked questions read was 56.6, the average number of chat messages sent was 14.4, 18 patients expressed interest in transplantation, and none chose parative care as a treatment modality.

In their conclusions, the researchers said, “The majority of participants who completed the program decided on home modality for treatment of ESRD and expressed interest in referral for kidney transplant evaluation. The pilot program suggests increased update of home-based ESRD treatment modalities, with potential significant impact on health-care costs.”

PCI versus Optimal Medical Management in Patients with Advanced Chronic Kidney Disease

Coronary artery disease is a common comorbidity in individuals with advanced chronic kidney disease (CKD). Patients with CKD and coronary artery disease may benefit from cardiovascular procedures, such as percutaneous coronary intervention (PCI), that require use of intravenous contrast. However, use of contrast dye may result in contrast-induced nephropathy (CIN). In patients with advanced CKD, CIN may precipitate the need for long-term dialysis therapy (hemodialysis).

PCI is frequently used in patients with CKD with unstable coronary syndromes, where a survival advantage with early intervention has been demonstrated. However, in the setting of stable symptomatic angina, both patient and physician factors contribute to decreased use of PCI, in that patient population, PCI is often delayed until required by acute indications or until initiation of dialysis therapy.

It is not certain whether this delay is appropriate in this patient population with high cardiovascular risk; there are few data comparing the relative risks and benefits of continued optimal medical therapy and PCI in patients with advanced CKD and stable angina. Aisha Khattak, MD, and colleagues recently conducted a patient-centered decision analysis designed to model upfront PCI compared with the options of deferring catheterization and continuing medical management only or preemptive hemodialysis followed by cardiac catheterization in patients with ongoing angina despite initial medical therapy. Results were reported in the American Journal of Kidney Diseases [2017;69(3):350-357].

The analysis involved a hypothetical cohort of individuals with advanced CKD, defined as CKD stages 4-5, estimated glomerular filtration rates ≤20 mL/min/1.73 m², and stable angina. A Markov model with a Monte Carlo simulation through 12 cycles (3 years of 3-month intervals) with 10,000 microsimulations was used to predict mean quality-adjusted life-years (QALYs). The interventions of interest were PCI first and medical management, or hemodialysis followed by PCI. The primary outcomes of interest were progression to hemodialysis therapy for those not in the preemptive hemodialysis strategy group, catheter infection, and death.

For the PCI-first strategy, the base model yielded mean QALYs of 1.103. For medical management, QALYs were 1.088; and for hemodialysis followed by PCI, QALYs were 1.182 for PCI first, 1.137 for medical management, and 0.914 for hemodialysis followed by PCI.

Preemptive hemodialysis was never the preferred strategy in any analysis. Probabilistic sensitivity analysis demonstrated that PCI was the preferred strategy >60% of the time. The expected value of perfect information using probabilistic sensitivity analysis was low at 0.0017.

In sensitivity analyses using higher probabilities of catheter infection, there was no plausible risk for infection even with temporary catheters that would result in medical management being favored over PCI first.

The researchers acknowledged some limitations to the analysis: (1) values for probabilities and utilities were estimated and/or derived from multiple sources, and several simplifying assumptions were made; and (2) generalizability may be limited due to some of the simplifications and assumptions as well as the decision to force individuals to remain with a catheter for 1 year, rather than allowing for sooner AVF placement.

In conclusion, the researchers said, “The decision about how to manage stable symptomatic angina in advanced CKD should be designed to maximize quality of life, at least from the patient perspective, but data to guide decision making from this vantage point are sparse. Our findings suggest that conservative approaches that limit the use of PCI in order to protect kidney function should be reevaluated and revisited. We believe that results of our study may help guide both physicians and patients to make a more informed decision and should mitigate apprehension in regard to risk of coronary intervention in patients with advanced CKD.”

**TAKEAWAY POINTS**

- Use of percutaneous coronary intervention (PCI) is low in patients with advanced chronic kidney disease (CKD) with stable symptomatic angina due to concern for precipitating the need for dialysis therapy.
- In a decision analysis, researchers used a Markov model with a Monte Carlo simulation to predict mean quality-adjusted life years (QALYs) with three strategies: PCI first, medical management, or preemptive hemodialysis followed by PCI.
- Mean QALYs were 1.103 for PCI first, 1.088 for medical management, and 0.67 for hemodialysis followed by PCI. PCI first was the preferred strategy >60% of the time.
Incidence of Renal Replacement Therapy in Elderly Patients in Nephrology Care

Recent estimates put the population prevalence of chronic kidney disease (CKD) in the United States at 13%. CKD affects patients of all ages, but there is a strong positive association of CKD with age; the prevalence of CKD among individuals >70 years of age is 50%. Among elderly patients diagnosed with stable CKD stage 3, management by the primary care physician following an initial nephrology consultation may be appropriate. However, elderly patients with advanced CKD at high risk for renal replacement therapy may benefit from nephrology care to facilitate RRT preparations such as timely fistula surgery.

Rapid decline in kidney function is a risk factor for RRT and death; recent studies found that patients with renal function loss >30% over an initial period of 2 years had an increased risk of end-stage renal disease (ESRD) regardless of age and estimated glomerular filtration rate (eGFR). However, the risk may differ in populations of unselected patients referred to nephrology care.

Ulrika Hahn Lundström, MD, and colleagues in Sweden recently conducted a study designed to examine the absolute risk of renal replacement therapy associated with a slow versus rapid progression of disease in a nationally representative sample of patients referred to nephrology care, taking into account the competing risk of death. Study results were reported online in BMC Nephrology [doi:10.1186/s12882-017-0473-1].

The study included all patients in the Swedish Renal Registry-Chronic Kidney Disease database with eGFR <45 mL/min/1.73 m² and a baseline visit between January 1, 2005, and December 31, 2011. Patients were followed until death, initiation of renal replacement therapy, or September 30, 2013, whichever came first. In all, there were 13,524 patients with an outpatient visit during the study period. Of those, 1653 were excluded due to age <18 years, data errors, acute kidney injury, or eGFR ≥45 mL/min/1.73 m². Another 3118 patients were excluded due to missing data on rate of disease progression (follow-up <1 year or only one measurement of serum creatinine within the prespecified time frame). The remaining cohort of 8771 patients had a mean age of 72 years, 64% were men, 26% were diagnosed with hypertensive kidney disease, 10% with glomerulonephritis, 21% with kidney disease of other specified causes, and 28% with unknown cause of uremia. Median eGFR was 20.2 mL/min/1.73 m² following the initial 1-year baseline period; the majority of patients were in CKD stage 4.

During the initial year, the estimated median progression rate was –8.8%, or an absolute median decline by –1.71 mL/min/1.73 m². Most of the patients experienced declining renal function; however, 35.1% had no change or an improvement in eGFR during the first year. Those defined as fast decliners (highest tertile, > -18.7% decline/year) were younger, had lower eGFR at baseline, lower hemoglobin, higher albumin-creatinine ratio, and higher phosphate compared with patients who were defined as nonprogressors.

Following the initial year, median follow-up was 2.8 years. During follow-up, there were 2060 deaths (23.5%) recorded prior to initiation of renal replacement therapy. Among patients >75 years of age, the risk of death prior to renal replacement therapy initiation was nearly six times higher than among those <65 years of age. Female sex, body mass index >30 kg/m², and having diabetic kidney disease or glomerulonephritis versus hypertensive kidney disease were variables associated with lower risk of death. With the exception of patients >75 years of age, the absolute risk of death prior to initiation of renal replacement therapy was similar in fast progressors compared with slow progressors.

Nearly one-quarter of patients initiated renal replacement therapy (24.2%); 52.4% were event-free at the end of follow-up. Accounting for the competing risk of death, the most important risk factors of renal replacement therapy initiation were lower CKD stage, lower age, and a fast 1-year progression rate. There was an association between higher comorbidity score and diabetic kidney disease relative to hypertensive kidney disease and higher incidence on renal replacement therapy. In the extensively adjusted final model, women had a much lower incidence of renal replacement therapy compared with men.

The 5-year probability of renal replacement therapy initiation was highest in patients <65 years of age with a fast initial progression rate (51% in CKD stage 4 and 76% in stage 5), low overall in patients >75 years of age with a slow progression rate (7% for CKD stage 3b, 13% for CKD stage 4, and 25% for CKD stage 5), and slightly higher in elderly patients with a fast initial progression rate (28% in CKD stage 4 and 47% in CKD stage 5) or with diabetic kidney disease.

Limitations to the study cited by the authors included not all patients in Sweden were included in the registry database, and exclusion of patients with fewer than two creatinine measurements and those who died within one year.

The researchers concluded by saying, “In this nationwide registry study of 8771 referred patients with CKD stage 3b-5, the risk of renal replacement therapy was high in younger patients with fast initial progression rate. Furthermore, the cumulative incidence of renal replacement therapy was generally low among elderly, slowly progressing patients even in advanced CKD stages. Thus, for planning, treating, and preparing the right patients for renal replacement therapy, following the slope of eGFR is important.”

Researchers in Sweden conducted an observational study of patients in the Swedish renal registry to examine the absolute risk of renal replacement therapy associated with a slow versus rapid disease progression, taking into account the competing risk of death.

There was an association between a fast initial progression rate and a higher risk of initiation of renal replacement therapy.

The 5-year probability of renal replacement therapy was highest in patients <65 years of age with a fast initial progression rate (51% in CKD stage 4 and 76% in CKD stage 5).
Home Telemonitoring of Patients with Chronic Kidney Disease

Worldwide, the majority of health-care expenditures are attributed to chronic illness. Management of patients with chronic illness involves multiple care providers, often at multiple locations. Coordination of care in the nephrology setting is particularly important; studies have documented that coordinating care between healthcare providers is associated with earlier nephrology referral, resulting in reduced morbidity, mortality, overall cost, and the number of consultations.

Home telemonitoring is a promising model for care coordination, in part because active patient participation is a central component. The model improves communication between patients and healthcare professionals and promotes early detection of declines in health status. In the nephrology setting, there have been studies evaluating the efficacy of home telemonitoring in home dialysis patients, but there are few data regarding home telemonitoring of patients with chronic kidney disease (CKD) before and after renal replacement therapy.

Researchers in France are conducting a pragmatic randomized, controlled trial to compare home telemonitoring with usual care in three populations of CKD patients. Nathalie Thilly, MD, and colleagues provided the rationale and study design of the trial online in *BMC Nephrology* [doi:10.1186/s12882-017-0529-2].

The trial, eNephro [NCT02082093], will include patients with CKD stage 3B/4 (population 1, n=320); patients with stage 5D CKD on dialysis (population 2, n=260); and patients with stage ST CKD treated with transplantation (population 3, n=260). Study participants are recruited from five hospitals and three not-for-profit providers managing self-care dialysis in three administrative regions in France.

The primary outcome of interest is the cost-effectiveness of the telemonitoring model to improve specific outcomes: clinical and biological parameters, and perceived health status.

Inclusion criteria are age ≥18 years; ability to use a tablet device (alone or with assistance); population 1: stabilized stage 3B or stage 4 CKD with nephrology management of <3 years; population 2: stage 5D CKD treated by home-care peritoneal dialysis or out-center hemodialysis; population 3: stage ST CKD treated by renal transplantation for 3 to 12 months. Exclusion criteria are dialysis after renal transplantation failure; organ transplantation other than kidney; and life expectancy <1 year.

Eligible patients are randomly assigned to either the intervention or control group and have an inclusion visit 1 month following enrollment. The visit includes a physical examination, blood and urine tests, and therapeutic adjustment as needed. The follow-up period is set at 12 months. Patients undergo an intermediary visit at 6 months and a final end-of-study visit at 12 months. The final visit includes a standard nephrology consultation and completion of study questionnaires measuring quality of life, anxiety/depression, compliance, and system acceptability (for the telemedicine group).

The intervention (eNephro) is an eHealth application designed for each population of patients with nephrology management of <3 years; population 2: stage 5D CKD treated by home-care peritoneal dialysis or out-center hemodialysis; population 3: stage ST CKD treated by renal transplantation for 3 to 12 months. Exclusion criteria are dialysis after renal transplantation failure; organ transplantation other than kidney; and life expectancy <1 year.

Eligible patients are randomly assigned to either the intervention or control group and have an inclusion visit 1 month following enrollment. The visit includes a physical examination, blood and urine tests, and therapeutic adjustment as needed. The follow-up period is set at 12 months. Patients undergo an intermediary visit at 6 months and a final end-of-study visit at 12 months. The final visit includes a standard nephrology consultation and completion of study questionnaires measuring quality of life, anxiety/depression, compliance, and system acceptability (for the telemedicine group).

The intervention (eNephro) is an eHealth model technology specifically developed for the care of patients with all stages of CKD. It is web-based and housed on secure servers to ensure the security, confidentiality, integrity, sustainability, availability, reversibility, and traceability of collected data. The system includes a shared electronic medical record, a secure messaging application for communication between healthcare professionals and patients, an agenda for scheduling medical visits, and a tele surveillance application designed for each population studied. The system also includes clinical decision tools for analyzing patient data.

When analysis of the clinical and biologic data indicates with high probability an alteration of a patient's health status, an alert is generated prior to the development of clinical manifestations. The alerts are designed to provide early detection of the risk of dehydration/hyperhydration; poor blood pressure control; elevated proteinuria; poor anemia control; occurrence of a complication, recognized with predefined symptoms.

The study will test the hypothesis that home telemonitoring enables improved control of clinical and biologic parameters, and improves perceived health status. The improved control should limit emergency consultations and hospitalizations, resulting in decreased healthcare expenditures. The cost savings will compensate for the financial investment needed to implement the telemonitoring model.

The researchers said, “This study can be expected to identify barriers and facilitators for implementing a home telemonitoring system as well as profiles of patients most likely to benefit from this new care system.”
Complications of Urgent-Start Peritoneal Dialysis

Peritoneal dialysis offers benefits to patients with end-stage renal disease (ESRD) in terms of lifestyle flexibility and preservation of residual kidney function. However, worldwide, most patients with uremia are treated with hemodialysis. Reasons for the underutilization of peritoneal dialysis include a low level of experience initiating the modality in patients with ESRD, particularly those with severe symptoms of uremia and volume overload.

Urgent start peritoneal dialysis, defined as initiating the therapy earlier than 2 weeks following catheter insertion, has garnered increased attention over the past 10 years. Allowing for expedited insertion of a peritoneal dialysis catheter and initiation of the therapy within days may offer a cost-saving method of treatment for ESRD patients requiring urgent dialysis.

However, peritoneal dialysis is associated with complications that need to be addressed, according to Damin Xu, MD, and colleagues. Of particular concern are mechanical complications associated with the shorter break-in period of urgent-start peritoneal dialysis. Data on risk factors have been inconsistent and limited to date. Dr. Xu et al. conducted an observational cohort study designed to examine the prevalence and risk factors of mechanical complications related to abdominal wall and catheter, respectively, among patients with urgent-start peritoneal dialysis therapy at Peking University First Hospital, Peking University, Beijing, People’s Republic of China. Results were reported online in the American Journal of Kidney Diseases [doi.org/10.1053/j.ajkd.2016.12.021].

The study included all patients who were treated with urgent-start peritoneal dialysis from January 2003 to May 2013. The outcomes of interest were the presence of mechanical complications related to abdominal wall or catheter, including hernia, hydrothorax, hydrocele, subcutaneous leak, pericatheter leak, catheter malposition, omental wrap, and obstruction. Urgent-start peritoneal dialysis was defined as initiation of peritoneal dialysis therapy within 7 days after catheter insertion.

A total of 922 patients were enrolled; follow-up continued for a median of 31.3 months. Of the 922 participants, 51.4% (n=474) were women; mean age was 59.1 years. Diagnoses were diabetic nephropathy (33.4%, n=308); glomerulonephritis (23.6%, n=218); hypertensive nephropathy (18.5%, n=171); chronic tubulointerstitial nephropathy (8.8%, n=81); polycystic kidney disease (2.0%, n=18); and other causes (13.7%, n=126).

Approximately half of the participants initiated peritoneal dialysis therapy within 1 day of catheter placement. At the end of the study, 42.6% (n=393) had died, 11.6% (n=117) transferred to hemodialysis therapy; 8.7% (n=80) received a transplant, 1.1% (n=10) were lost to follow-up, and 36.0% (n=332) continued on peritoneal therapy.

At a median follow-up of 5.2 months, 8.8% (n=44) of the patients developed abdominal wall complications, resulting in an incidence of 1.5 per 100 patient-years. Hernia accounted for 55% of those complications, including 18 inguinal hernias and six umbilical hernias. Other abdominal wall complications were hydrothorax (25%, n=11), hydrocele (14%, n=6), subcutaneous leak (5%, n=2), and pericatheter leak (1%, n=1).

Of the 24 patients with hernias, four switched to hemodialysis therapy and two received adjustments to their peritoneal dialysis regimens. The other 18 underwent surgical repair, two of whom subsequently experienced a relapse requiring a second surgery and then continued with peritoneal dialysis. Of the 11 patients with hydrothorax, none underwent surgery; 10 switched to hemodialysis therapy, and one continued on peritoneal dialysis therapy after adjustments for lower infusion volume.

Overall, 21 of the 44 patients with abdominal wall complications transferred to hemodialysis therapy. Peritoneal dialysis technique survival at 1, 2, and 3 years was 72.5%, 55.6%, and 48.4%, respectively, in those with abdominal wall complications and 97.5%, 95.3%, and 91.8% in those without complications.

There were 189 patients enrolled after 2010. Of those, 9.5% (n=18) presented with catheter complications: 13 with catheter obstructions caused by fibrin or constipation, four catheter shifts, and one omental wrap. All occurred during the first month of peritoneal dialysis therapy, resulting in an incidence of 2.5 per 100 person-years. Conservative therapy relieved all 13 catheter obstructions. Of the four patients with catheter shifts, three underwent repositioning with laparoscopy or surgery. The other patient underwent repositioning with laxatives only. The patient with omental wrap switched to hemodialysis therapy.

Predictors of abdominal wall complications were identified comparing patients with and without complications. There were no differences between the two groups in age, blood pressure, biochemistry markers, or the break-in period. Patients with complications were more likely to be men, have a history of more abdominal surgeries, and have lower exchange volume.

Following adjustments, male patients had a 5-fold higher risk for developing complications (hazard ratio [HR], 5.41; 95% confidence interval [CI], 2.15-13.59; P=.001) compared with female patients. Patients with a history of abdominal surgery had a 2-fold higher risk for developing complications (HR, 2.34; 95% CI, 1.04-5.26; P=.04) compared with those without.

Of the 189 patients enrolled after 2010, those with catheter-related complications were younger and had lower levels of hemoglobin than those without catheter-related complications. In logistic regression models, only age was associated with catheter complications in both crude and multivariable analyses. There was an association between each year older and 5% fewer catheter complications (HR, 0.95; 95% CI, 0.91-0.98; P=.005) following adjustment.

Study limitations cited by the authors included the possibility of selection bias due to the cohort study design, the small number of end points, the limited statistical power limiting the ability to observe potential effects, and changes in management of patients with chronic kidney disease over the course of the study.

“In conclusion, in a large cohort of Chinese patients, urgent-start peritoneal dialysis was a safe and practicable approach for eligible patients with uremia, with an acceptable prevalence of mechanical complications. Male sex and history of abdominal surgery are recognized as risk factors for abdominal wall complications. More studies with large sample sizes are needed to verify our findings. Hopefully, the ready availability of peritoneal catheter placement will promote the initiation of peritoneal therapy for all patients with ESRD,” the researchers said.

TAKEAWAY POINTS

- Due to short break-in periods, patients undergoing urgent-start peritoneal dialysis therapy are at risk for mechanical complications, including abdominal wall complications and catheter-related complications.

- Chinese researchers conducted an observational cohort study of 922 patients on urgent-start peritoneal dialysis. Of the 922 patients, 44 developed abdominal wall complications, an incidence rate of 1.5 per 100 person-years.

- Of the 189 patients enrolled after 2010, 18 presented with catheter complications, an incidence rate of 2.5 per 100 person-years.
Associations between eGFR and Reduced Cognitive Function Stronger in Older Individuals

Reduced estimated glomerular filtration rate (eGFR) and albuminuria have both been shown to be associated with lower cognitive performance in older individuals. The association is not consistent, however. Reduced eGFR may lead to the accumulation of neurotoxins or it may represent lifetime exposure to cardiovascular disease (CVD) risk factors to CVD itself. Albuminuria may be a biomarker of generalized endothelial dysfunction.

There are few data on whether the associations between reduced eGFR and albuminuria and reductions in cognitive function are limited to older patients or also may be experienced by patients 40 to 65 years of age. Remy J. H. Martens, MD, and colleagues conducted cross-sectional analyses of a prospective population-based cohort study to examine the associations of eGFR and albuminuria with domains of cognitive function in individuals 40 to 75 years of age who participated in the Maastricht Study. Domains of interest were memory function, information processing speed, and executive function. The analyses also aimed to determine whether the associations differed by age [American Journal of Kidney Diseases. 2017;69(2):179-191].

Of the total cohort in the Maastricht Study, 2987 were eligible for inclusion in the current analyses. None of the participants was on dialysis treatment. Mean age was 59.6 years, and 41.2% had higher vocational education or university level education. Participants with higher albuminuria and those with lower GFR estimated by the Chronic Kidney Disease-Epidemiology Collaboration serum creatinine and serum cystatin C equation (eGFRcr-cys) were older, more often male, were less educated, more often had type 2 diabetes mellitus and CVD, and had a worse CVD risk profile.

Urinary albumin excretion was <15 mg/24 hours in 81.7% of participants (n=2439), 15 to <30 mg/24 hours in 10.3% (n=309), and ≥30 mg/24 hours in 8.0% (n=239). Those with higher urinary albumin excretion had lower performance on each of the cognitive domains.

Following adjustment for age, sex, glucose metabolism status, and educational level and using urinary albumin excretion < 15 mg/24 hours as the reference category, there was an association between urinary albumin excretion ≥30 mg/24 hours and lower overall cognitive performance, lower information processing speed, and borderline statistically significant lower memory function. Following further adjustment for other variables (waist circumference, total to high-density lipoprotein cholesterol ratio, triglyceride level, use of lipid-modifying medication, smoking status, alcohol consumption, urinary albumin excretion [categorical] or eGFRcr-cys [continuous], office systolic blood pressure, use of antihypertensive medication, prevalent CVD, and depression), the association was attenuated, but remained statistically significant for overall cognitive performance and information processing speed. There was no association between continuous albuminuria and cognitive performance following full adjustment.

The association between continuous albuminuria and cognitive performance was stronger at older age. There was no association with eGFRcr-cys cognitive performance at age 50; in individuals 70 years of age, eGFRcr-cys was associated with lower overall cognitive performance and borderline statistically significantly lower memory function and executive function.

The analyses did have some limitations, according to the authors, including the cross-sectional design that limited causal inferences; the inability to exclude residual confounding despite adjustment for an extensive series of potential confounders; the somewhat arbitrary nature of classifying individual cognitive tests into multiple cognitive domains; differences between participants in the Maastricht Study with missing data (not included in the analyses) and those with complete data (included in the analyses); and the absence of direct measurements of GFR, precluding any definitive conclusions on the differences between the eGFR formulas and their associations with cognitive decline.

“In conclusion,” the researchers said, “in the entire study population, albuminuria was independently associated with worse cognitive performance, in particular within the domain of information processing speed, whereas eGFRcr-cys was not associated with cognitive performance. However, both albuminuria and eGFRcr-cys were more strongly associated with cognitive performance in older individuals.”
Fall Injury Risk in Older Adults Increases after Dialysis Therapy Initiation

Among community-dwelling older adults, falls are the leading cause of injury-related hospitalizations and may lead to disability and death. More than one in three older adults fall each year, and nearly half of those falls result in injury. Earlier studies have demonstrated that serious fall injuries commonly occur among older adults with chronic kidney disease (CKD); higher levels of albuminuria may confer higher risk. Studies focusing on older adults receiving treatment with long-term dialysis demonstrated that nearly half of those patients may fall each year. Falls among older adults on dialysis therapy are associated with greater risk of serious injury and death compared with those who do not fall. However, those earlier studies of falls in this patient population have focused on prevalent dialysis patients recruited from single dialysis centers. It is possible that the increase in rates of serious fall injuries is due to initiation of dialysis therapy occurring in the setting of acute illness, indicating worsening health and functional decline.

According to Laura C. Plantinga, PhD, and colleagues, an awareness of rates of serious fall injuries before and after initiation of dialysis therapy may be an aid in identification of periods of high risk that could benefit from multicomponent strategies to reduce falls. The researchers conducted a retrospective cohort study of claims data from the 2 years spanning dialysis therapy initiation among patients initiating dialysis therapy from 2010 to 2012.

The study was designed to determine the rate of serious fall injuries among older adults receiving hemodialysis and whether the rate differs before and after dialysis initiation. The researchers also examined whether the association of timing with serious fall injury differs according to patient characteristics. The researchers reported study results in the American Journal of Kidney Diseases [2017;70(1):76-83].

Definitions for serious falls were derived from diagnostic codes for falls in combination with fractures, brain injuries, or joint dislocation. Estimates of incidence rate ratios, both overall and stratified, for post-versus pre-dialysis therapy initiation periods were made using generalized estimating equation models with a negative binomial link.

The researchers analyzed data on claims from 81,653 Medicare beneficiaries 67 to 100 years of age with end-stage renal disease (ESRD). Mean age was 77 years, 47% were women, and 66% were non-Hispanic white. Fifty-five percent had diabetes and 88% had comorbid hypertension. Approximately 10% were unable to walk at initiation of dialysis therapy, 18% required assistance with activities of daily living, and 14% were institutionalized.

Compared with those without a fall injury prior to initiation of dialysis therapy, beneficiaries who had at least one fall injury prior to initiation of dialysis therapy were older, more likely to be women, more likely to be white, more likely to have dialysis therapy initiated during an inpatient hospitalization, and more likely to be unable to walk or transfer, need assistance with activities of daily living, and be institutionalized. Likewise, compared with those without serious fall injuries following initiation of dialysis therapy, beneficiaries with at least one serious fall injury post-dialysis therapy initiation were older, more likely to be women, and more likely to be white.

“In conclusion, serious fall injuries are common among older Medicare beneficiaries receiving hemodialysis. The rate of serious falls was higher in the post-versus the pre-dialysis therapy initiation period for all patients. Patients at lowest risk for falls by other factors, such as those who were younger, able to walk and transfer, and not institutionalized and had better nutritional status had the highest differential risk across the two periods. Risk for falls following dialysis therapy initiation should be discussed with patients initiating dialysis therapy, and strategies to reduce fall and associated injury risk should be considered in this high-risk population,” the researchers said.

**TAKEAWAY POINTS**

- Serious injury due to a fall is common among community-dwelling older adults; researchers conducted a retrospective cohort study to examine the rates of falls among Medicare beneficiaries initiating hemodialysis therapy.

- In the pre-dialysis therapy initiation period, the annual rate of serious falls was 64.4 per 1000 patient-years. In the period following initiation of dialysis therapy, the rate was 107.9 per 1000 patient-years.

- Patients who were younger, had nephrology care prior to development of end-stage renal disease, had albumin levels >3 g/dl, were able to walk and transfer, did not need assistance with activities of daily living, and were not institutionalized had greater magnitude in the relative rates of serious fall injuries in the pre- and post-dialysis initiation periods compared with relative rates among their counterparts.
Treating Hypertension in Transplant Recipients: Chlorthalidone versus Amlodipine

In kidney transplantation recipients, hypertension following the transplant has been shown to be an independent risk factor for transplant failure. Hypertension after transplantation is also associated with increased risk for cardiovascular disease and mortality. Contributors involved in development of hypertension after transplant include donor, recipient, and transplantation factors. Patients treated with calcineurin inhibitors (CNIs) have been shown to have increased incidence of hypertension following the introduction of cyclosporine.

Mechanisms including systemic and renal vasoconstriction contribute to CNI-induced hypertension, possibly through endothelin 1, and impaired vasodilation, explaining the efficacy of dihydropyridine calcium channel blockers (CCBs) for the treatment of CNI-induced hypertension. However, CNI-induced hypertension has also been shown to be salt sensitive. The salt sensitivity of CNI-induced hypertension has recently been linked to the activation of one specific sodium transporter in the kidney, suggesting that thiazide diuretics may be effective in treating CNI-induced hypertension.

In one study, results demonstrated that thiazide diuretics did effectively lower blood pressure in kidney transplant recipients; however, treatment was associated with higher incidences of hyperkalemia and hypokalemia. Thiazide diuretics may be used infrequently in this patient population due to concerns related to efficacy at lower estimated glomerular filtration rates or adverse events such as gout and glucose intolerance. Arthur D. Moes, MD, and colleagues in The Netherlands recently conducted a randomized noninferiority crossover trial to compare the effectiveness of chlorthalidone with that of amlodipine for treatment of hypertension in a population of kidney transplant recipients.

Both drugs were effective antihypertensive agents following kidney transplantation; chlorthalidone may be preferable in patients with proteinuria or edema. Amlodipine was chosen as the second treatment due to concerns related to efficacy at lower estimated glomerular filtration rates or adverse events such as gout and glucose intolerance. The researchers were testing the hypothesis that chlorthalidone is equally effective as amlodipine for the treatment of hypertension following kidney transplantation. They reported results in the American Journal of Kidney Diseases [69(6):976-804].

The study was a randomized noninferiority crossover trial, with a margin of noninferiority of –2.8 mm Hg. The primary outcome of interest was average daytime (9 am to 9 pm) ambulatory systolic blood pressure. Patients meeting eligibility criteria were randomly assigned to start with chlorthalidone, 12.5 mg, or amlodipine, 5-10 mg, for 8 weeks, followed by a 2-week washout period, and then 8 weeks with the remaining drug. There were six scheduled study visits: the start and end of each treatment period and 2 weeks after starting each drug. Blood pressure was measured every 5 minutes for 30 minutes at the 2-week visit.

Eighty-eight patients underwent the initial ambulatory blood pressure measurement. Of those, 56% (n=49) had daytime systolic blood pressure >140 mm Hg. Those 49 patients started in the study. A total of 41 patients completed the study and were included in the analysis. Five patients stopped the study during the chlorthalidone treatment for adverse events; one patient stopped during the amlodipine treatment for an adverse event, and two stopped during the washout period.

Of the 49 patients who completed the study, 76% had received a living donor kidney transplant and 88% had tacrolimus and mycophenolate mofetil as the immunosuppressive regimen. None of the patients used glucocorticoids. Rates of dose escalation were similar: 37% (n=15) for amlodipine versus 41% (n=17) for chlorthalidone (P=0.8). Average daily drug doses were 6.4 mg for amlodipine and 16.4 mg for chlorthalidone.

Both study drugs reduced daytime systolic blood pressure (amlodipine: from a mean of 150 to 137 mm Hg; chlorthalidone: from a mean of 151 to 141 mm Hg). There was no statistical difference in blood pressure response between the two drugs. Chlorthalidone appeared to cause a carry-over effect (lower baseline systolic blood pressure for patients receiving amlodipine as second treatment). Despite similar blood pressure responses, there was significant reduction in proteinuria with chlorthalidone (median change, 169 to 116 mg/g; mean 32% reduction vs 4% increase during amlodipine). In addition, urinary calcium was nearly halved during chlorthalidone, whereas it increased during amlodipine. Estimated glomerular filtration rate (eGFR) increased during treatment with chlorthalidone (from 58 to 50 mL/min/1.73 m²); eGFR increased during treatment with amlodipine (from 54 to 58 mL/min/1.73 m²). However, in the 23 patients who completed treatment order two (first chlorthalidone), eGFRs normalized during the washout and amlodipine treatment periods. Five patients who continued treatment with chlorthalidone following completion of the study had initial decreases in eGFR (from 75 to 64 mL/min/1.73 m²) that later stabilized (65 mL/min/1.73 m² after a mean of 21 weeks of treatment with chlorthalidone).

Treatment with chlorthalidone also increased serum uric acid levels (without attacks of gout) and levels of hemoglobin A1c. Treatment with amlodipine increased tacrolimus predose concentrations.

With the exception of physician-assessed edema, both drugs were well tolerated. Physician-assessed edema increased during treatment with amlodipine from 10% to 34%, but decreased during chlorthalidone treatment from 22% to 10%. No acute rejections were diagnosed or treated during the study period.

Limitations cited by the researchers included the open-label design and the lack of an intention-to-treat analysis. In addition, many eligible patients declined to participate in the study due to the four ambulatory blood pressure monitoring requirements, limiting the generalizability of the findings. In summary, the researchers said, “Both amlodipine and chlorthalidone are effective antihypertensive drugs after kidney transplantation; chlorthalidone may be preferable in patients with proteinuria or edema. Combination therapy with half doses of each agent may also be an interesting approach, which requires future study.”
Cognitive Impairment Among Kidney Transplant Recipients

As many as 50% to 87% of patients on maintenance dialysis experience cognitive impairment, influencing quality of life, employment rates, adherence to treatment, hospital admissions, health care costs, morbidity, and mortality. Kidney transplantation offers advantages in quality of life and survival over dialysis, but kidney transplant recipients have several risk factors for cognitive impairment, including comorbid illness, depression, and lower levels of physical activity.

There are few data on the prevalence of cognitive impairment in kidney transplant recipients. Aditi Gupta, MD, and colleagues at the University of Kansas Medical Center in Kansas City recently conducted a cross-sectional study designed to screen eligible kidney transplant recipients in order to evaluate the prevalence of cognitive impairment in that patient population. The researchers also sought to evaluate the factors associated with cognitive impairment in transplant recipients. Results of the study were reported online in BMC Nephrology [doi:10.1186/s12882-017-0570-1].

The single-center study followed eligible adult kidney transplant recipients at the University of Kansas Kidney Transplant Clinic. Eligible patients who attended the clinic between May 2015 and June 2016 were approached to participate in the study. To minimize the acute effect of high dose steroids, surgery, and possible post-operative complications, cognitive assessments were conducted only after the patient was at least one month post-transplant. Cognition was assessed during the clinic visit for post-transplant care.

The Montreal Cognitive Assessment (MoCA) was used to assess cognition. The MoCA is a validated, clinic-based tool that samples from various domains of cognition. The researchers used the MoCA due to its focus on executive function, a domain more commonly affected in kidney disease. The MoCA consists of a single page and can be completed in less than 10 minutes. The original English version was used.

Of the 297 eligible patients approached for the MoCA test, 265 met inclusion criteria and completed the MoCA. Of those, 226 had complete data and were included in the analysis. Mean age of the 226 participants was 54 years, 39% (n=89) were female, 73% (n=173) were white, and 58% (n=130) had an education level of college or above. Approximately half were obese (n=115), with a body mass index (BMI) ≥30 kg/m2; mean estimated glomerular filtration rate (eGFR) was 52 mL/min/1.73 m2. Average time on dialysis prior to transplant was 2.3 years and average time since transplant was 3.4 years. Three percent of the participants had a history of stroke and 21% had a history of coronary artery disease.

Results of the MoCA found that 58% reached criteria for cognitive impairment. Mean age was higher among those with cognitive impairment compared with those without cognitive impairment (P<.001) and a lower proportion of female participants had cognitive impairment (P=.02). In multivariable analysis, older age was associated with higher risk for cognitive impairment. The researchers also analyzed the prevalence of cognitive impairment stratified by 5-year age groups; the results showed an increased prevalence of cognitive impairment with older age, but also a high prevalence of cognitive impairment even in patients <50 years of age.

There were some study limitations cited by the authors, including the cross-sectional design that precluded conclusions regarding cause and effect and provided no information on whether cognitive impairment was worsening, improving, or stable; excluding patients who did not speak English may have limited the generalizability of the findings; not assessing depression in the study; and obtaining the clinical data from chart review.

“The prevalence of cognitive impairment in kidney transplant recipients is high. In contrast to the general population even younger transplant recipients have a high prevalence of cognitive impairment. This information should be taken into consideration during patient education and monitoring of medical adherence. Further research is needed to understand the pathophysiology and consequences of cognitive impairment in transplant recipients. Strategies to help kidney transplant recipients cope with cognitive deficits should be developed,” the researchers said.

TAKEAWAY POINTS

- Among 226 participants in a study to assess the prevalence of cognitive impairment among kidney transplant recipients, the prevalence of cognitive impairment was 58%, based on scores on the Montreal Cognitive Assessment (MoCA).
- In multivariable analysis, there was an association between lower scores on the MoCA and older age, male gender, and absence of diabetes.
- There was an increased prevalence of cognitive impairment with older age among kidney transplant recipients, but also a high prevalence of cognitive impairment even in individuals <50 years of age in that patient population.
Veltassa Approved in European Union Market

In late July, Relypsa, Inc., announced that Veltassa® (patiromer) received approval from the European Commission for its Marketing Authorization Application. Patiromer is indicated for the treatment of hyperkalemia (elevated levels of blood potassium).

Veltassa is the brand name for patiromer in both the United States and Europe; it is approved for marketing in all 28 European Union (EU) countries and in Iceland, Liechtenstein, and Norway. In a press release, Relypsa, a Vifor Pharma Group company, announced that Vifor plans to launch Veltassa in Europe by the end of 2017 or in early 2018.

Veltassa was approved by the US FDA in October 2015 for the treatment of hyperkalemia; it was the first new medicine approved for hyperkalemia in more than 50 years. Marketing authorization applications for Veltassa have been submitted and are under review in Switzerland and Australia. There are also plans for submission of applications in other markets worldwide.

Scott Garland, president of Relypsa, said, “The European approval of Veltassa marks the first regulatory approval for this important medicine outside the United States, further validating our innovative polymer science. In the United States, we are encouraged by the growing acceptance and uptake of Veltassa by clinicians and patients. In the 18 months since we launched Veltassa, more than 33,000 patients with hyperkalemia, a serious and often chronic health concern, have been treated with it. We look forward to working with our colleagues at Vifor Pharma Group to help bring Veltassa to patients in Europe, where a new daily treatment for hyperkalemia is needed.”

In the EU, Veltassa is indicated for the treatment of adults with hyperkalemia. The Summary of Product Characteristics notes that this includes patients who develop hyperkalemia while being treated with renin angiotensin aldosterone system (RAAS) inhibitor therapy. At baseline, nearly all patients treated with Veltassa in the clinical development program were on RAAS inhibitors.

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Montefiore Health System Receives NIH Research Grant

For the 42nd consecutive year, the Division of Pediatric Nephrology at the Children’s Hospital at Montefiore (CHAM)/Albert Einstein College of Medicine has received funding from the National Institutes of Health. The funding is designated for training the next generation of investigators working to create advances in science and discovery related to kidney health. The $1.2 million T32 training grant will be used to fund postdoctoral fellows and CHAM/Einstein over 5 years, protecting their time to conduct research.

Over the past 42 years, NIH funding has benefited more than 50 postdoctoral trainees at CHAM/Einstein, providing them with mentorship and guidance from the CHAM/Einstein researchers as they worked together on a variety of translational and clinical research projects leading to improved care for children with kidney disorders and diseases, according to a press release from the Montefiore Health System.

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Refusal Rates of Deceased Donor Kidneys Vary Widely

In a recent study reported in the Clinical Journal of the American Society of Nephrology, researchers found that kidneys from deceased donors are typically offered and declined many times prior to being accepted for transplantation. In addition, the study found differences in such refusals according to patient and donor characteristics and may be a contributing factor in racial and ethnic disparities in access to transplantation.

The researchers analyzed data on the seven million deceased donor adult kidney offers

Renal Dialysis Device Market Expected to Grow to $26 Billion

In 2016, renal dialysis equipment accounted for more than 55% of the market value of the nephrology and urology devices market. Dialysis-related equipment totaled more than $17 billion, and is expected to grow to more than $26 billion by 2026. According to a press release from GlobalData, nearly 60% of renal dialysis patient growth will be driven by the emerging markets of China, Brazil, and India, which is expected to account for 48% of the population of patients on dialysis by 2026.

Andrew S. Thompson, PhD, director of therapy and analysis for medical devices at GlobalData, said, “This report indicates that renal dialysis equipment will maintain a lead in the nephrology and urology devices market; however, incontinence devices are an area to watch out for, given the projected increase in demand, coupled with a healthy product pipeline. For companies operating in the renal dialysis space, this level of growth presents a huge opportunity to maintain their competitive advantage by driving volume and value sales and profitability.”

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in the United States from 2007 to 2012 that led to eventual transplantation. The study population included 178,625 patients who were waitlisted for a deceased-donor kidney transplant and 31,230 deceased donors.

In the current study, kidneys from deceased donors were offered for transplantation a median of seven times before being accepted for transplantation. The most common reasons for refusal were factors related to the donor (age or donor quality) or because the minimal acceptable criteria for a transplant center were not met. After adjustment for waitlisted patient characteristics, donors, and transplant centers, male and Hispanic patients were 7% and 4% less likely to have kidneys accepted for them for transplant compared with female and white patients, respectively. There was wide variation in the likelihood of offer acceptance across transplant centers.

In an article in Medical News Today, Anne Huml, MD, lead author of the study, said, “By recognizing these differences, centers may be able to evaluate their acceptance practices to have the greatest impact on shortening times. Gaining a better understanding of offer refusals may also allow policy makers to develop and disseminate information about best practices to centers with low acceptance rates.”

### Post-ED Discharge Mortality and AKI

Thirty-day outcomes among patients discharged from the emergency department with acute kidney injury (AKI) tend to be poor; poor outcomes include increased risk of mortality, according to a retrospective review of medical records reported in the Clinical Journal of the American Society of Nephrology.

Patients with AKI upon discharge were 60% more likely to die within 30 days compared with those without AKI (relative risk [RR], 1.60; 95% confidence interval [CI], 1.2-2.0; P<.001). Patients excluded from the study were those admitted to the ED specifically for AKI. Another study finding demonstrated that patients discharged from the ED with AKI were less likely to die within 30 days compared with those with AKI who were hospitalized (RR, 0.30; 95% CI, 0.2-0.3; P<.001).

In an article on Medpage Today, the researchers said, “These findings highlight the accuracy of ED clinicians in discerning subtle clinical differences in patients with AKI. Sicker patients destined for worse outcomes were appropriately hospitalized. Nonetheless, the adverse outcomes of AKI following an ED discharge are clearly highlighted when such patients were compared to a similar cohort of patients without AKI.”

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### Major Meetings 2017–2018

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<thead>
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<th>Event</th>
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<th>Location</th>
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<tr>
<td><strong>Annual Dialysis Conference</strong></td>
<td>March 3-6, 2018</td>
<td>Orlando, Florida</td>
<td><a href="http://annualdialysisconference.org">http://annualdialysisconference.org</a></td>
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<tr>
<td><strong>National Kidney Foundation Spring Clinical Meetings 2018</strong></td>
<td>April 10-14, 2018</td>
<td>Austin, Texas</td>
<td><a href="http://www.kidney.org/professionals/news/meetings">www.kidney.org/professionals/news/meetings</a></td>
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<td><strong>American Transplant Congress 2018</strong></td>
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<td><a href="http://www.atcmeeting.org">www.atcmeeting.org</a></td>
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<td><strong>American Society of Nephrology Kidney Week 2018</strong></td>
<td>October 23-28, 2018</td>
<td>San Diego, California</td>
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ACUTE KIDNEY INJURY

Diagnoses Associated with Hospital-Acquired AKI

Researchers in France conducted a retrospective analysis of the association between hospital-acquired acute kidney injury (AKI) and each International Classification of Diseases-Tenth Revision (ICD-10) category to identify the diagnoses associated with AKI. The analysis included data on hospital stays for 126,736 unique individuals. The analysis was performed by Anne-Sophie Jannot, MD, PhD, et al.

The primary factors associated with hospital-acquired AKI are hemodynamic impairment and surgical procedures, and five clusters of diagnoses were revealed: sepsis, heart diseases, polytrauma, liver disease, and cardiovascular surgery. The ICD-10 code corresponding to AKI was recorded in 30% of the cases with hospital-acquired AKI identified, and in those cases, 20% of the diagnoses associated with hospital-acquired AKI corresponded to kidney disease (tubulointerstitial nephritis, necrotizing vasculitis, or myeloma cast nephropathy).

“Our approach, derived from phenome-wide association studies, is a valuable way to comprehensively identify and classify all of the diagnoses and clusters of diagnosis associated with hospital-acquired AKI. Our analysis delivers insights into how diagnoses associated with hospital-acquired AKI evolved over time. On the basis of ICD-10 codes, hospital-acquired AKI appears largely underestimated in this academic hospital,” the researchers said.

CHRONIC KIDNEY DISEASE

Estimating Decline in Kidney Function with Anthropometric Measures of Body Fat

Researchers, led by Magdalena Madero, MD, conducted the Health Aging and Body Composition Study designed to compare the association of computed tomography (CT) and anthropometric measures of obesity with kidney outcomes. CT measures included visceral abdominal fat (VAT), subcutaneous adipose tissue (SAT), and intermuscular fat area (IMAT); anthropometric measures included waist circumference (WC) and body mass index (BMI).

The study included 2483 participants; mean age was 74 years, 49% were men, 39% were black, 59% were hypertensive, and 15% were diabetic. Seventeen percent of the study population experienced decline in kidney function; incident chronic kidney disease also occurred in 17% of those at risk. There were associations between decline in kidney function and SAT, VAT, IMAT, BMI, and WC in continuous models. There was a significant association between VAT and CKD with regard to decline in

INDICATION

AURYXIA® (ferric citrate) is the non-calcium, non-phosphate, non-iron supplement approved by the FDA for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

IMPORTANT SAFETY INFORMATION

Contraindication: AURYXIA is contraindicated in patients with iron overload syndromes.

Iron Overload: Iron absorption from AURYXIA may lead to excessive elevations in iron stores, especially when concomitant IV iron is used.

Accidental Overdose of Iron: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of the reach of children.

Patients with Gastrointestinal Bleeding or Inflammation: Safety has not been established.

Pregnancy Category B and Nursing Mothers: 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 milk. There is possible infant exposure when AURYXIA is taken by a nursing woman.

The most common adverse events with AURYXIA were diarrhea (21%), nausea (11%), constipation (8%), vomiting (8%), and abdominal pain (4%). The most common adverse reactions were the most common reason for discontinuing AURYXIA (14%).

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Safety and tolerability were assessed in the pivotal study over 52 weeks. Patients received AURYXIA in 2 of 3 (2 tablets 3 times per day with meals

Overdose: AURYXIA contains iron. Iron absorption from AURYXIA may lead to excessive elevations in iron stores, especially when concomitant IV iron is used.

Accidental Overdose of Iron: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of the reach of children.

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Safety and tolerability were assessed in the pivotal study over 52 weeks. Patients received AURYXIA in 2 of 3 (2 tablets 3 times per day with meals.
kidney function ($P=.01$).

In conclusion, the researchers said, “Anthropometric measures of body fat appear to provide as consistent estimates of kidney function decline risk as CT measures in elders.”
gglomerular filtration rate or progression to end-stage renal disease over a median of 1.0 and 2.0 years of follow up, respectively. Following adjustment for potential confounders, there was an association between every doubling of GDF-15 level and a 72% higher and 65% higher risk of progression of kidney disease in C-PROBE and SKS participants, respectively. “These results show that circulating GDF-15 levels strongly correlated with intrarenal expression of GDF-15 and significantly associated with increased risk of CKD progression in two independent cohorts. Circulating GDF-15 may be a marker for intrarenal GDF-15-related signaling pathways associated with CKD and CKD progression,” the researchers said.

Using Rescaled Renal Biomarkers to Diagnose Impaired Renal Function

Clinica Chimica Acta. 2017;471:164-170

Equations to estimate glomerular filtration rate (GFR) rely on serum creatinine, a major contributing value in those calculations; equations based on serum cystatin C have also been developed. Hans Pottel, PhD, and colleagues recently conducted a study to examine the relationship between rescaled levels of those renal biomarkers and measured GFR (mGFR). The study assessed the diagnostic ability of rescaled serum creatinine and rescaled serum cystatin C levels to detect impaired kidney function in 8,884 participants from 12 cohorts with measured GFR. The researchers calculated sensitivity and specificity of the rescaled biomarkers to identify kidney disease with reference to a fixed (60 mL/min/1.73 m²) as well as an age-dependent threshold for mGFR.

Results of the study demonstrated that there is a close relationship between the upper reference limit of 1.33 for rescaled renal biomarkers and the age-dependent threshold for defining kidney status by mGFR. Sensitivity and specificity for the rescaled biomarkers is nearly 90% for all ages. Specificity in children and sensitivity in older adults were observed when the fixed threshold of 60 mL/min/1.73 m² for mGFR was used.

In conclusion, the researchers said, “Impaired kidney function can be diagnosed by rescaled biomarkers instead of GFR equations using the fixed threshold of 1.33 for all ages, consistent with an age-dependent threshold of mGFR.”

DIALYSIS

2014 Data from the National Healthcare Safety Network

Dialysis Event Surveillance


The US Centers for Disease Control and Prevention conducts surveillance to track bloodstream and vascular access infections among people receiving outpatient hemo-
dialysis. Duc B. Nguyen, MD, and colleagues summarized 2014 data submitted to the National Healthcare Safety Network Dialysis Event Surveillance in a report in the Clinical Journal of the American Society of Nephrology. There are three types of events reported by dialysis facilities: (1) bloodstream infections; (2) intravenous antimicrobial starts; and (3) pus, redness, or increased swelling at the hemodialysis vascular access site.

The network received dialysis event data in 2014 from 6005 outpatient dialysis facilities. A total of 160,971 events were reported, including bloodstream infections (n=29,516); intravenous antimicrobial starts (n=149,722); and pus, redness, or increased swelling at the site of hemodialysis vascular access (n=38,310). Of the 29,516 bloodstream infections, 76.5% (n=22,576) were considered related to vascular access. Most of the bloodstream infections (63.0%) and access-related bloodstream infections (69.8%) occurred in patients with a central venous catheter.

In summary, the researchers said, “The 2014 National Healthcare Safety Network Dialysis Event data represent nearly all United States outpatient dialysis facilities. Rates of infection and other dialysis events were highest among patients with a central venous catheter compared with other vascular access data. Surveillance data can help define the epidemiology of important infections in this patient population.”

Changes in Frailty Over Time in Patients on Hemodialysis


Patients receiving hemodialysis often experience frailty, leading to adverse outcomes. There are few data relating to changes in frailty over time and the factors associated with those changes. Kirsten L. Johansen, MD, and colleagues conducted an analysis of data from an end-stage renal disease cohort study; study participants had frailty assessments at baseline, and at 12 and 24 months.

The distribution of frailty scores was similar at each evaluation. Most scores changed, with patients improving as often as worsening. There were associations between higher frailty scores and Hispanic ethnicity and diabetes; there was an association between higher serum albumin and lower frailty scores. Patients whose serum albumin increased over time were less likely to become frail.

In conclusion, the researchers said, “There was substantial year to year variability in frailty scores, with approximately equal numbers of patients improving and worsening. Markers of inflammation and hospitalization were independently associated with worsening frailty. Studies should examine whether interventions to address inflammation or posthospitalization rehabilitation can improve the trajectory of frailty.”

Geriatric Nephrology

Palliative Care Consultations for Patients with Renal Disease versus Other Illnesses


According to Vanessa Grubbs, MD, MPH, and colleagues, patients with end-stage renal disease receive palliative care less often that patients with other serious illnesses. Dr. Grubb et al. conducted an observational study designed to compare characteristics and outcomes of hospitalized patients in the United States who had a palliative care consultation for renal disease versus other serious illnesses.

Of 33,183 patients in a database collected by the Palliative Care Quality Network on patients who had a palliative care consultation, the researchers identified 1057 patients who had renal disease as the primary reason for the consultation. Mean age for those with renal disease was 71.9 years versus 72.8 years for patients with other serious illnesses.

At the time of the consultation, both groups of patients had similarly low mean Palliative Performance Scale scores and reported similar levels of anxiety (moderate to severe). With the exception of anxiety, the symptoms improved similarly following consultation regardless of diagnosis. Although change in code status was also similar between the two groups, fewer patients in the renal disease group were referred to hospice compared with patients with other serious illnesses (30.7% vs 37.6%, respectively; P<0.001).

In summary, the researchers said, “Hospitalized patients with renal disease referred for palliative care consultation had similar palliative care needs, improved symptom management, and clarification of care as those with other serious illnesses.”

Transplantation

Aldimuzumab Prior to Kidney Transplantation in Pediatric Patients

Pediatric Transplantation. doi: 10.1111/petr.12941

A recent single-center, retrospective review was conducted by Michael M. Kaabak, MD, and colleagues to test the hypothesis that administration of alemtuzumab several weeks prior to kidney transplantation in pediatric patients (7 months-18 years of age) could eradicate peripheral lymphatic cells and promote donor-specific acceptance. The patients received a kidney transplant between September 2006 and April 2010.

Immunosuppression protocol included two 30 mg doses of alemtuzumab: one given 12 to 29 days before transplantation and one at the time of transplantation. Maintenance immunosuppression was based on a combination of low-dose calcineurin inhibitor and mycophenolate, with steroids tapered over the first 5 days post-transplantation. Follow-up continued for 7.8 years, and protocol biopsies were taken at 1 month, and 1, 3, and 5 years following transplantation.

Kaplan-Meier 8-year patient and graft survival rates in the patients treated with cyclosporine were 82.0 and 71.6, respectively; in patients treated with tacrolimus, 8-year patient and survival rates were 97.2 and 83.8, respectively. Thirty-five percent of patients treated with cyclosporine developed biopsy-proven acute rejection, compared with 8% of those treated with tacrolimus.

In conclusion, the researchers said, “Alemtuzumab pretreatment prior to living related donor kidney transplantation, followed by maintenance immunosuppression with tacrolimus and mycophenolate mofetil, is associated with reasonable long-term results in pediatric patients.”

Comparison of Outcomes between Antibody Induction Therapies after Transplantation

Journal of the American Society of Nephrology. 2017;28(7):2188–2200

Recipients of kidney transplantation often receive antibody induction. Neel Koyawala and colleagues utilized data from the Procurement and Transplantation Network linked with Medicare claims to compare outcomes between three induction therapies for kidney transplant recipients. The primary outcomes of interest were death and death or allograft failure. Secondary outcomes included death or sepsis, death or lymphoma, death or melanoma, and healthcare resource utilization within 1 year.

The researchers generated 1:1 pairs of alemtuzumab-rabbit antithymocyte globulin (rATG) (n=5330 pairs) and basiliximab-rATG (n=9378 pairs) recipients. Compared with rATG recipients, alemtuzumab recipients had higher risk of death and death or allograft failure (hazard ratio [HR], 1.14; 95% confidence interval [CI], 1.03–1.26; P<.01) and death or allograft failure (HR, 1.18; 95% CI, 1.09–1.28; P<.001). Compared with rATG recipients, basiliximab recipients had higher risk of death (HR, 1.08; 95% CI, 1.01–1.16; P=.03) and death or lymphoma (HR, 1.12; 95% CI, 1.01–1.23; P=.03).

“This observational evidence indicates that, compared with alemtuzumab and basiliximab, rATG associates with lower risk of adverse outcomes, including mortality,” the researchers said.
From the Field

New Bill Cuts Facility Certification Delays and Expands Telehealth Options

Ridiculously lengthy delays in getting new dialysis facilities certified might finally be going away. H.R. 3178, sponsored by ten members of the House of Representatives, would allow new facilities to be certified by government-approved agencies other than Medicare.

In this age of few agreements between political parties, this bill appears to have great appeal to both parties as it is cosponsored by six Republicans and four Democrats. At the time of this writing, the bill has been moving quickly through the legislative process. The bill was introduced in the House on July 11, sailed through committees, and was passed by the House 14 days later. The bill was sent to the Senate the next day.

The fact that the bill is cosponsored by three Representatives from Texas is no surprise since the Lone Star State has experienced some of the most extreme delays in the country. It is not uncommon for new facilities in Texas to wait 18 months to two years to be surveyed by the state. Delays of a year or more are also being experienced in other states.

The delays in certification have scared away potential investors in dialysis for years. From time to time I am contacted by physicians, current end-stage renal disease (ESRD) facility owners, and other potential investors who ask me about the revenue they could expect from opening a new outpatient dialysis facility. The call normally goes well until I mention the huge delays they will experience in becoming certified.

Potential investors are often in disbelief when I describe the delays. A common response I receive is, "Wait a minute. You are telling me that after I spend more than a million dollars building a facility, buying equipment, and hiring at least an RN and a medical director, that I have to start one or two patients and treat them while receiving little or no income for 18 to 24 months? That's crazy!"

As a result, these investors shift their money to another arm of healthcare and the number of independently owned facilities continues to drop. Dialysis chains have also become frustrated with the delays and yet no one has been able to get anything done until now.

INITIAL CERTIFICATION VISITS IN 90 DAYS

Once the bill is enacted, within 90 days the secretary of Health and Human Services must begin accepting requests from national accreditation bodies who can meet the conditions and requirements necessary for certifying outpatient dialysis facilities. Within 180 days of enactment, new ESRD facilities must receive an initial survey within 90 days. Thus, 6 months after the enactment of the bill, new facilities will have to wait no longer than 3 months to receive their initial visit from surveyors.

MONTHLY VISITS TO HOME PATIENTS VIA TELEHEALTH

Another key element in the bill is a provision that would allow physicians to treat more home dialysis patients via telehealth beginning in 2019. Current laws make it almost impossible for most renal practitioners to treat patients via telehealth because neither the patient’s home nor dialysis facility are included as approved originating sites. The new bill approves both of those sites and allows home patients to receive their monthly ESRD-related visits via telehealth with greater frequency.

Under the bill, face-to-face visits would be required during a home patient’s first 3 months of treatment, but after that, such visits would only be required once every 3 months.

KEEP CURRENT ON REGULATIONS

One of the biggest stumbling blocks to maximizing your practice’s or facility’s revenues is when physicians, clinicians, managers, and/or administrators are unaware of new reporting requirements that affect reimbursement. Even more frustrating is when key people refuse to change their ways after being informed of the new requirements.

Keeping yourself informed and adapting to new regulations will improve the financial health of your practice or facility. The time and cost spent on staying informed and making needed changes will pay significant dividends over time.

Rick Collins is the chief operating officer of Sceptre Management Solutions, Inc., a company specializing in billing for outpatient ESRD facilities, nephrology practices, and vascular access. Your questions are welcome and he can be reached at rcollins@sceptremanagement.com or 801.775.8010.
Associated Costs Lower for Endovascular AVF Creation

Arteriovenous fistula (AVF) is the preferred access type, offering longer access survival, lower risk of mortality, and reductions in rate of infection. AVF also requires fewer interventions following successful maturation and use. Recent studies have suggested that maturation and maintenance of function may require two or more additional procedures following the initial AVF creation. Additional procedures are associated with a proportion of AVF failures, requiring patients to rely on temporizing measures until stabilization prior to creation of a functional AVF. An alternative to the traditional open surgical approach for AVF creation, a new endovascular catheter-based system (the everlinQ endoAVF system) has been developed that uses a minimally invasive method to create an endoAVF. The system creates a side-to-side anastomosis without open surgery or dissection of vessel. The NEAT (Novel Endovascular Access Trial) was conducted to assess the efficacy and safety of endoAVF creation in patients with stage 4 chronic kidney disease requiring vascular access for hemodialysis.

Marc Glickman, MD, and colleagues conducted a retrospective observational study designed to provide insight into the potential economic savings associated with the use of endoAVF.

Initial Dialysis Session Duration Associated with Patient Outcomes

Following expansion of Medicare coverage to patients with end-stage renal disease (ESRD) 40 years ago, the average number of hours per hemodialysis session has decreased from 6 hours in 1973 to 3.5 to 4 hours in 2010. The decline is explained in part by the improved efficiency of dialyzers; however, there are few data on the clinical consequences of shorter session duration on patients on maintenance hemodialysis.

Endovascular AVF May Be Viable Option for Vascular Access in Hemodialysis Patients

The recommended method of vascular access is the surgical creation of an AVF, a technique developed in 1966. At present, only 14% of patients with end-stage renal disease initiate hemodialysis with an AVF; in addition, prevalent use of AVFs is low in many regions worldwide. Factors contributing to underuse of AVF include long cumulative waits for surgical consultation and creation of the AVF, a process that can take from 3 to 10 weeks to complete; inconvenient and time-consuming preoperative visits; patient refusal of surgery; surgical risk; and high early thrombosis rates (12% to 26%). Further, maturation of the AVF can be challenging, requiring use of bridging catheters and an average of 1.5 to 3.3 procedures to allow fistula usability. Using an endovascular approach to create an AVF may reduce time to functional AVF and lower the incidence of infection. The everlinQ endoAVF system may provide an alternative for patients with limited access options.

Marc Glickman, MD, and colleagues conducted a retrospective observational study designed to provide insight into the potential economic savings associated with the use of endoAVF.
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