Nocturnal and Home Dialysis in the United States

By Michael A. Kraus

In December 2014 the US Food and Drug Administration (FDA) granted clearance for a dialysis device to be used for nocturnal home dialysis. This step should open the door for patients with ESRD to have access to a full array of dialysis modalities, including in-center therapies of self-care, thrice-weekly and nocturnal dialysis, and home therapies consisting of continuous cycling peritoneal dialysis, continuous ambulatory peritoneal dialysis, conventional home hemodialysis, portable low-flow hemodialysis, short daily dialysis, and nocturnal home dialysis 3.5 to 6 nights per week. Multiple devices are on the horizon, and flexibility of therapy should be an option for a majority of ESRD patients.

A properly educated family and patient can decide which therapy offers the greatest advantage to the patient. The patient and family can balance the issues of frequency, timing, quality of life, and mortality. It is appropriate to empower patients with the honest outcomes of dialysis and help them determine the best individualized course of action.

Although there has been an increase in home hemodialysis since 2004, many more patients could benefit from the improved quality of life and flexibility offered by increased-frequency home dialysis. It is interesting that when queried, health care providers in the dialysis industry would overwhelmingly choose a home therapy for themselves. The nephrology community is left trying to explain the disparity between our own desires and how patients are treated in the United States.

Since 2004 there has been a steady gain in the use of home dialysis in the United States associated with FDA clearance of the NxStage System One, a low-flow dialyzer system for home use. This device has brought increased ease of use, lower utility costs, and portability. Home dialysis in the United States has become a predominately short daily therapy with increased frequency but remains limited in its use. Data from the United States Renal Data System show an increase in use from 1831 prevalent ESRD patients in 2004 to 7923 in 2012, or an increase of just 0.5 percent to 1.8 percent of the prevalent ESRD patient population.

Thrice-weekly in-center dialysis has shown an improvement in premature mortality recently, but the mortality still is around 20% yearly. In-center patients experience postdialysis fatigue, increasing left ventricular hypertrophy (LVH), sleep apnea, restless legs, hypertension with multiple agents, high hospitalization rates, increasing rates of infection and death, and increases in hospitalization with the 48-hour intradialysis period.

Increased-frequency dialysis has been demonstrated to improve quality of life scores, decrease post-dialysis recovery, improve sleep, improve BP with decreased medications, decrease LVH, and improve mortality when compared with in-center or peritoneal dialysis. Increased-frequency nocturnal dialysis also improves these factors. In addition, nocturnal dialysis improves sleep apnea and allows a normalized diet with the discontinuation of phosphate binders. Nocturnal dialysis moves the burden of therapy to bedtime, increasing freedom from therapy during daylight hours and decreasing the overall burden of therapy for patients and their partners. Both therapies can eliminate the 48-hour break from the dialysis schedule. Increasing use of increased-frequency home therapies will require better knowledge among nephrologists, improved education and communication with patients, and removal of barriers to use by patients and health care givers.

Nocturnal dialysis is not just more of the same. Prescriptions for nocturnal dialysis vary based on frequency and device. Nocturnal therapy can be delivered in the patient’s home with the low-dialysate device (FDA cleared with NxStage System One) or a conventional hemodialysis device.

Conventional dialysis requires electrical and plumbing changes to the home. A dedicated 20-A circuit for dialysis must be hardwired, and water treatment with a softener, charcoal filter, and reverse osmosis or DI (deionization) treatment is required. The differences between nocturnal and thrice-weekly in-center dialysis are decreased blood flow, decreased dialysate flow, and a higher calcium bath with increased frequency.

Low-flow dialysis with the NxStage System One is a different prescription. It uses lower dialysate volumes of 20 to 60 L per treatment. The lower dialysate flow increases the saturation of dialysate composition and allows for lower volumes. No studies have determined the best dialysate volumes. At Indiana University, for short daily treatments, we prescribe a minimum of 20 L for all patients and roughly 20% of body weight for women and 25% for men. We increase this for 5 days versus 6 days. Generally, nocturnal dialysis at home is prescribed with increased frequency. If 5 days or more are prescribed, we prescribe 30 L for smaller patients and 45 to 60 L for larger patients. The dialysate volume can be increased if phosphorus is not controlled. Conversely, the dialysate volume can be decreased if phosphorus is low despite increasing dietary intake of phosphorus. For nocturnal dialysis, a heparin pump is generally used, and the dialysate bath is 2K and 4O to 45 lactate. Blood speed is 250 to 300 mL/min, and the dialysate flow is adjusted to allow for 6 to 8 hours of dialysis to meet the patient’s needs. Water treatment occurs with online generation and storage of ultrapure dialysate. This requires much less water and electricity.

Despite the many advantages of increased-frequency home dialysis, there are significant concerns. Access infection and necessity for procedures are increased in some studies. Dislodgement of venous access is a potentially fatal complication and must be avoided, particularly in the sleeping patient. Infection can be addressed by proper education and reeducation on technique and the importance of proper technique. We have markedly decreased infection by addressing these factors in training and reeducation monthly in the clinic. Noninfectious complications are expensive and morbid. A thorough physical examination in the clinic and education of patients in the signs of decreased flow are mandatory.

With proper education, reeducation, and training at Indiana University Health Dialysis, our home program enjoys a very low rate of infectious and noninfectious complications. Over the past 18 months, the Indiana University Health home program has had a rate of 4 thromboses in 97 patient months (1 thrombosis every 24.25 months) for arteriovenous (AV) grafts and 5 thromboses in 841 patient months (1 thrombosis every 168.2 months) for AV fistulas. During the same period, the two in-center units have had a rate of 48 thromboses in 762 patient months (1 every 15.88 patient months) for AV fistulas. Fistulas fared better than AV grafts, and increased-frequency home access fared better than in-center access with thrombosis.

The infection rate in the home dialysis unit is better than expected as well. Over the past 18 months, the home unit AV fistula infection rate is 1 episode every 210.2 months (4/841 months). The AV graft infection rate is 1 every 19.4 months (5/97 months).
Peritoneal Dialysis: An Update for 2015

By John Burkart

In 2015, the overwhelming majority of patients with treated ESRD in the United States are treated with in-center hemodialysis (CHD), whereas peritoneal dialysis (PD) is the predominant modality used by home dialysis patients. Overall, this is not markedly different from the historical distribution of modality use: most patients use CHD. However, not only has the observed historical decline in percentag es of patients using PD (1995–2009) stabilized, but the percentage of those using PD has actually been increasing since 2010 (1).

This trend is most likely a result of the new prospective payment system for Medicare patients, which has “bundled” the payment and treatment so that the overall payment amount per week of typical dialysis is the same for CHD and PD, effectively removing any unintended financial incentives that had favored the use of CHD. This trend may also be fueled by clinical observations over the past decade, such as those showing that in the United States, improvements in survival for patients using PD have outpaced those in CHD; so that the differences in 5-year survival, if any, are probably not clinically meaningful (2–4). As a result, the PD population in the United States has almost doubled since 2008 (from about 23,000 in 2008 to about 46,000 in 2014 in the 10 largest providers) (1).

Some have been concerned that because of lack of infrastructure and of nurses’ and physicians’ experience, this new growth would be associated with a reported increase in mortality or a decrease in techni que survival. To date there have been no published data to support that concern. One unexpected problem associated with this rapid growth in PD is the inability of the current manufacturers of peritoneal dialysate fluids to keep up with the demand for bags needed for cycl er therapy. This is being addressed by industry, national societies, and the US Food and Drug Administration. Most patients now use cycl er therapy (automated peritoneal dialysis [APD]), one of the submodalities of PD, because of issues related to their quality of life. Although there could be differences in selected patient outcomes between these two submodalities of PD, there are no consistently reported clinically relevant differences in clinical outcome between APD and manual exchanges (5).

Peritoneal dialysis access-related issues

Catheter-related issues remain a reason for transfer to CHD. Most PD catheters are placed in the operating room by surgeons using open dissection. This requires general anesthesia, does not allow direct visualization of the peritoneal cavity and true pelvis, and may frequently result in primary catheter dysfunction because of the inability to identify anatomic arrangements that interfere with catheter function. In addition, because of difficulties in scheduling surgeons and operating rooms, delays in peritoneal catheter placement have often necessitated the initiation of dialysis with CHD by use of a temporary vascular access and delaying the start of PD.

The degree of success with the historical open dissection approach and other techniques (such as the percutaneous needle–guide wire approach, with or without imaging guidance, and the laparoscopic technique) is provider related and is associated with matching the appropriate placement technique with the appropriate patient. Ancillary procedures such as tacking of redundant omentum (omentopexy) and lysis of adhesions that can potentially be performed by the advanced laparoscopic approach cannot be done with open dissection. In one report, when the advanced laparoscopic technique was used for catheter implantation, only 3 percent of patients transferred to hemodialysis as a result of catheter failure, compared with 17 percent nationally (6), and one center reported that 99 percent of catheters were problem free at 24 months (7). These ancillary procedures, however, are needed in only about one third of all patients, so it may be reasonable to avoid costs and minimize the risk of general anesthesia by using other implantation techniques.

Coincident with the recent growth in PD use are data such as the estimates from the 2013 Medicare Physician/Supplier Procedure use summary, which suggests that the use of open dissection for PD catheter placement is decreasing (now 22 percent of catheters placed) whereas the use of other techniques such as surgical laparoscopy (26 percent in 2007; 52 percent in 2013) is increasing. In addition, to facilitate the need for short-term and urgent PD catheter placement and avoidance of scheduling conflicts, general anesthe sia, and overall costs, percutaneous needle–guide wire techniques (with imaging guidance, generally by interventional radiologists [22 percent], or without imaging guidance, generally by interventional nephrologists [4 percent]) have become more commonly used for placing PD catheters.

The important issue when other techniques are used is how the subcutaneous portion of the PD cath eter is placed, because the ability to salvage rather than replace a PD catheter when there is a complication or nonfunction is related to the correctness of the original placement. Therefore, to improve overall outcomes and minimize costs, we should foster the use of a multidisciplinary approach to PD catheter implantation. This multidisciplinary approach does not necessarily involve all physicians at once but does imply that different physician specialists must work together to promote the delivery of seamless medical care. PD catheters are currently placed by surgeons, interventional radiologists, and interventional nephrologists.

Most practicing interventional radiologists and interventional nephrologists did not learn how to place PD catheters during training and are learning on the job. Moreover, surgery, radiology, and nephrology residency and fellowship programs continue to be poorly prepared and largely inadequate with respect to teaching PD catheter access procedures. In a survey of surgical residency programs in the United States, it was found that fellows typically place only two to five catheters during their training, and when asked, 38 percent of fellowship directors stated they could not provide more training. Unfortunately, 77 percent of PD programs start fewer than 10 patients with PD each year (8). As a result, catheter dysfunction remains a problem for PD patients and one of the major causes for morbidity and transfer to hemodialysis. Educating the person who places the PD access is important, and efforts are being put in place by major national dialysis providers and the Interna-

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