Peritoneal Dialysis Catheter Weighted Anchor

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Summary

The technology is a peritoneal dialysis (PD) catheter weighted anchor, which can be used to secure the active tip of a PD catheter into the most dependent portion of the pelvis, known as the cul de sac. PD catheters work best when they are located within the cul de sac. The dialysate fluid tends to gravitate into the cul de sac which promotes optimal drainage through the PD catheter. In addition, this location is void of omental fat and bowel loops. Omentum and bowel around the PD catheter can cause painful infusions and impair the catheter patency by the omentum wrapping around the catheter, as well as promoting fibrin ingrowth into the PD catheter. A common cause of PD catheter failure is migration (dislocation) out of the cul de sac, which has been reported in the literature to occur between 12.7 and 35% of cases. In our experience, using 3D imaging techniques, PD catheter migration occurs in up to 80% of cases. No commercially available device or technique exists to prevent PD catheter migration with the percutaneous insertion method. Our device was developed to secure a percutaneously placed PD catheter within the cul de sac and to decrease the frequency of PD catheter failure due to migration.

This device could be produced as an add-on modification of existing commercially available PD catheters, or it could be incorporated into the end of a new PD catheter as a single unit. Either way, it is a versatile design, which can be placed percutaneously or surgically, and can be used by interventional radiologists, interventional nephrologists, or surgeons.

Peritoneal dialysis (PD) is a low cost, and often physiologically beneficial, option for many patients with end stage renal disease (ESRD). Its utilization is increasing in the U.S., as 9% of ESRD patients were using PD in 2010 and 10% were using it in 2014. This increase is projected to continue, as the benefits of PD are increasingly realized. Patients on PD experience a greater sense of well-being due to an improved steady state in terms of hemodynamics, extracellular fluid volume, coagulation, nutritional status, and general health compared to hemodialysis. PD is a home dialysis therapy, which is associated with greater patient independence and improved quality of life. PD differs from hemodialysis (HD) in that no artificial membrane is used, as the patient's peritoneum (lining of the abdominopelvic cavity) serves as the semipermeable membrane needed to exchange between the extracellular fluid and the artificial dialysate fluid placed into the peritoneal cavity through a tunneled single lumen catheter. However, the two most common reasons that patients on PD transfer to hemodialysis are infection and PD catheter malfunction.

Interventional radiologists are an underutilized source for PD catheter placement. The interventional radiology technique involves imaging guidance, familiarity with catheter and guide-wire manipulation, and minimally invasive methods to ensure that the PD catheter is quickly and safely placed into the cul de sac. However, many interventional radiologists believe that PD catheter placement is a frustrating experience due to the high PD catheter malfunction rate and have not embraced the procedure.

If the PD catheter weighted anchor is proven to decrease the failure rate of PD catheters, it could markedly increase the number of PD catheters placed and the number of ESRD patients using PD, particularly as interventional radiologists adopt the technology. Chronic kidney disease affects 14.8% of adults in the U.S., and the number of patients progressing to ESRD (needing dialysis or a kidney transplant to survive) is increasing, representing 678,383 patients in 2014. We believe that PD

will account for a greater amount of Medicare spending on ESRD patients, which was $32.8 billion in 2014. Section 1881(b)(14) of the Social Security Act requires a bundled prospective payment system (PPS) for renal dialysis services furnished to Medicare beneficiaries for the treatment of ESRD effective January 1, 2011. The ESRD PPS provides a patient-level and facility-level adjusted per treatment (dialysis) payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a beneficiary's home. The bundled per treatment payment includes drugs, laboratory services, supplies and capital-related costs related to furnishing maintenance dialysis. The ESRD PPS provides a training add-on for home and self-dialysis modalities and additional payment for high cost outliers when there are unusual variations in the type or amount of specific medically necessary care, when applicable. This represents yet another financial incentive for PD, which is a lower cost alternative to HD.

Investigation and Funding

Since this technology will likely be considered by the U.S. Food and Drug Administration (FDA) to be a Class I medical device, an Investigation Device Exemption (IDE) will likely be required before testing the device in humans. For the 2017/2018 academic year, we were awarded an institutional grant of $48,000 to investigate this device. We used tungsten carbide as the metallic weight for this device.

The first phase of the investigation analyzed the durability and stability of the device, while dwelling in saline baths for up to one year. We measured elements that could diffuse or leak out of the device by ultraviolet visible photometry and inductively coupled plasma mass spectroscopy (ICP-MS). The ICP-MS test is sensitive to measuring concentrations of one part in 10 million. The results confirmed that the device is stable and durable, without any significant leak of tungsten.

The second phase analyzed the feasibility of percutaneous insertion and retrieval, infusion functionality, and positional stability of the device attached to PD catheters in four separate cadavers of varying body sizes. Ten devices were attached to peritoneal dialysis catheters and inserted percutaneously into the cul de sac (rectovesical space) and removed percutaneously in four fresh (non-embalmed, expiration time of less than 48 hours, but chilled to a temperature of 40 degrees Fahrenheit) cadavers.

All infusions were performed with room temperature normal saline. Catheter placement into the cul de sac was confirmed in all cases with multiple obliquity fluoroscopic and digital peritoneograms using iodinated contrast media, as well as rotational CT (XperCT, Philips Healthcare, Cambridge, MA). During infusions and drains, all via gravity, table heights were standardized to -9 cm below isocenter for infusions and +18 cm above isocenter for drains. Table height varied between +6 and +17 cm above isocenter, depending on the size of the abdominal girth during the rotational CT acquisitions. For all infusions, the top of the saline bag was 90 inches above the floor. For all drains, the saline bag was placed onto the floor.

Provocative maneuvers to test peritoneal dialysis catheter and device stability were performed, including infusion of normal saline to distend the peritoneal space in all cadavers, as well as 360-degree body rolls along the longitudinal axis in two cadavers. During this cadaver study, most catheters far exceeded this standard regarding flow rates, both during infusion and drainage. We were surprised that we obtained such high flow rates, given the problems anticipated using stiff cadavers with unprepared intestines. We attributed the high flow rates to the weighted anchor effect of the device, positioning the catheter within the cul de sac, which remained stable in position in all cases during infusion and drainage, as well in two cadavers which were subjected to the 360 degree longitudinal axis roll. All catheters and devices remained intact, and were easily inserted into the cul de sac, as well as retrieved percutaneously.