A Review of Evolving Dialysis Catheter Technologies

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ABSTRACT

Dialysis catheters continue to play a vital role in the delivery of hemodialysis to patients for both temporary vascular access, serving as a bridge to permanent access, and for long-term access for patients with end-stage renal disease (ESRD). During the past decade, there has been an emergence of technological advancements in the design of dialysis catheters in an attempt to reduce catheter malfunction, decrease infection rates, and improve their long-term efficiency. New improvements in catheter design are aimed at translating into improved catheter performance. This review article summarizes some of the novel catheter designs developed within the last decade.

KEYWORDS: Dialysis, end-stage renal disease, catheters, tunneled catheters

Objectives: Upon completion of this article, the reader will be able to analyze a comprehensive review on dialysis catheters.

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Due to the growing population of patients in need of hemodialysis (HD), the demand for central tunneled dialysis catheters has steadily increased. Dialysis catheters are necessary to provide temporary extracorporeal vascular access to facilitate correction of the metabolic derangements caused by renal dysfunction when an arteriovenous site is not available. An arteriovenous fistula (AVF) is still and should be the preferred method for HD because it has a lower complication rate.¹ However, the continued growth in the percentage of patients in the United States receiving dialysis via catheters has increased from ~13 to 25%.² Reasons for this increase include advanced patient age, comorbid conditions such as peripheral vascular disease and dia-

betes, and late referral to the nephrologists for creation of an AVF. Therefore, dialysis catheters are a continued necessity in some end-stage renal disease (ESRD) individuals, particularly in patients in whom arteriovenous access may be problematic, impossible, or delayed.

There continues to be a need for vascular access catheters to function well, have a low complication rate, and a long cumulative patency rate. From 1998 to 2006 the incidence rate of bacterial infection has increased steadily by ~2% every 2 years.³ There is also a high incidence of thrombosis with the use of dialysis catheters.⁴⁻⁶ These values indicate the need for further improvement in the development and optimal design of dialysis catheters.

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There is a wide variety of dialysis catheters available on the current market. Currently, many new dialysis catheters are being developed in an effort to decrease thrombosis and infection rates and to prolong the long-term outcome of catheterization. Thrombosis has long been a problem with dialysis catheters. One way this problem has been addressed is by the evolution of material technology. A transition has been made to using polyurethane or carbothane (a polyurethane/polycarbonate copolymer) rather than silicone because it allows for better catheter strength and softness, while still maintaining a large internal diameter. Additionally, there have been studies documenting an increase in infection risk attributable to silicone-based catheters^{7,8}; however, the overall comparisons have been inconclusive.⁹ The current trend is in developing carbothane-based dialysis catheters such as the Duraflow® (AngioDynamics, Queensbury, NY) because the added benefit is that this copolymer is resistant to chemicals (i.e., iodine, peroxide, or alcohols), thereby increasing the longevity of the catheter. Besides the use of material technology, some companies have added the use of antimicrobial coatings or antithrombogenic surface coatings to decrease the rate of infections and prevent thrombosis. Some of these strategies include coating the catheters with antibiotics or silver ion, using antibiotic ointment at the exit site and/or antimicrobial locking.

Additionally, HD machines require a high blood flow rate of 350 mL/min to achieve adequate hemodialysis.¹⁰ The tip of the catheter can be modified in attempt to achieve this goal after optimization of the lumen of the catheter. Optimization of the tip is also important for prevention of recirculation, preventing thrombosis and infection. The goal of this review is to summarize some of the currently available catheters recently developed to control infection and thrombosis rates, and also to review the latest in catheter tip design aimed at improving the efficiency and longevity of catheters.

INFECTION

Infection is a major cause of death in ESRD patients. Central vascular access devices are the most important independent risk factors for infection in patients on hemodialysis.¹¹ The relative risk of bacteremia is 7-fold higher in ESRD patients with vascular access catheters, than in ESRD patients with AVFs.¹² There is a 22 to 38% rate of metastatic complications, including endocarditis, septic arthritis, and epidural abscess or death in these patients.^{13,14} In relation to patients with fistulas, mortality is increased by 50% in diabetics, and by 70% in nondiabetic vascular access patients.¹⁵ The overall relative risk of infection-related death is 2-fold higher in patients with a chronic indwelling central venous access, than in those with fistulas.

The most frequent microorganisms isolated during catheter-associated bacteremia are *Staphylococcus aureus* and *Staphylococcus epidermidis*.^{13,16} These organisms enter the patient's bloodstream via the catheter tunnel tract site or via the catheter hub. A biofilm material surrounds the inner and outer surfaces of the catheter and serves as a culture medium. Femoral-vein catheters are also known to have a higher risk of infection than subclavian or internal jugular vein catheters¹¹; multiple-lumen catheters also have a higher risk of infection than do single-lumen catheters.¹⁷ Randomized studies have shown that the prophylactic use of intravenous antibiotics during placement of tunneled catheters is of no benefit.^{18,19} Rather, the prevention of catheter-related infections is related to sterile technique of catheter placement, daily catheter exit site care, and catheter management in the HD facility.²⁰

Within the first 30 days after placement, catheters become infected by external routes—mainly from the patient's skin microflora and the hands of the medical personnel. After the first 30 days, catheters become infected by internal routes including contamination of the catheter hub, which can lead to hematogenous spread and subsequent bloodstream infection. And finally, colonization of the indwelling catheter can occur via colonization from a distant, unrelated infection.

Tunneled versus Nontunneled Catheters

When acute renal replacement therapy is needed, nontunneled large-bore central venous catheters (CVCs) provide the easiest and quickest access for dialysis. However, it should be restricted to the first 1 or 2 weeks of hemodialysis. Prolonged catheter residence is correlated to a higher risk of catheter-associated bacteremia and central venous obstruction.

Tunneled cuffed catheters have a much lower bacteremia rate than that of temporary catheters.^{21–24} The use of a cuff placed in the subcutaneous tissue near the insertion site of a tunneled catheter allows for fibrous sealing of its skin entry, thus providing a barrier against infection by preventing migration of bacteria down the outer surface of the catheter. Insertion of a cuffed, tunneled catheter is recommended as soon as it is known that prolonged renal replacement therapy (more than 2 weeks of hemodialysis) is needed. However, even tunneled catheters can present major problems of infection because colonization can occur at the insertion site and/or invasion along the catheter hub.

Silver Coating

One strategy aimed at reducing infection rates in tunneled catheters was the addition of a silver coating, or the placement of a silver-impregnated cuff. This strategy evolved based on promising in vitro studies which showed

that a silver-sulfadiazine-chlorhexidine coating had a strong bactericidal effect and reduction in colonization. Some studies have shown that the addition of silver ions incorporated into a cuff which is attached to the catheter can reduce infection rates^{25,26}; however, these results are from nontunneled catheters. Clinical studies from chronic dialysis catheters remain inconclusive: A prospective randomized trial performed by Trerotola et al²⁷ did not show any significant benefit in reducing the infection rate using this silver-coated catheter. This is in contrast to a more recent study performed by Bambaer et al²⁸, which did show an overall decrease in bacterial colonization rates in the silver-based antimicrobial catheters, compared with uncoated catheters. Overall, the interest in silver-coated catheters has somewhat dwindled as newer coating technologies have been developed.

Antibiotic Ointments

The use of either mupirocin or povidone-iodine or other antibiotic ointment at the exit site until it is healed is also advocated.²⁹ However, some polyurethane catheters have developed mechanical breakdown after prolonged exposure to antibiotic ointment (Bard Peripheral Vascular, Tempe, AZ).²⁰ This has led to the interest in using a polyurethane/polycarbonate copolymer (such as carbothane) in the construction of newer dialysis catheters because these copolymers are resistant to a majority of chemicals, such as iodine, alcohols, and peroxide. Polyurethane-based catheters, on the contrary, react strongly to alcohols and the only antibiotic ointment that can be used with these catheters is Neosporin[®] (Johnson & Johnson, New Brunswick, NJ).⁹ Silicone-based catheters are similar to copolymer-based catheters and can be used with a variety of antibiotic ointments.

Both topical and intraluminal antibiotics reduce the rate of bacteremia as well as the need for catheter removal secondary to complications. One potential problem is that emerging antimicrobial resistance can lead to loss of efficacy.³⁰

Antibiotic Locks

According to the 2006 K/DOQI Clinical Practice Guidelines, catheter exchange should be performed within 72 hours of initiating systemic antibiotic therapy in patients with catheter-related bacteremia (CRB), as systemic antibiotics alone can only clear ~30 to 50% of CRB episodes.³¹ However, more recent reports have reported that antibiotic lock solutions (ABL) can clear CRB without removal or exchange of the catheter. Because each manipulation or exchange of a catheter can promote fibrosis, leading to both stenosis and thrombosis with eventual loss of access, clearing CRB without removal or exchange is one of the most important new developments in hemodialysis catheters.

ABL is a high concentration of antibiotic with or without the addition of an anticoagulant agent, such as tissue plasminogen activator (tPA) or heparin, that can reside within the catheter lumen, exposing the biofilm in the internal lumen of the catheter to the ABL's antibacterial and sometimes anticoagulant properties.

In a systematic review and meta-analysis of 11 randomized controlled trials that compared single or combination antimicrobial catheter lock solutions with heparin or another antimicrobial, the outcomes assessed were catheter-related bloodstream infections and the need for catheter removal. Antibiotic catheter lock solutions were found to significantly reduce catheter-related bloodstream infections and reduce catheter removal rates in patients undergoing hemodialysis when compared with heparin lock alone.³² All studies showed benefit for lock solutions in treating catheter-related bloodstream infections. Locks that contained gentamicin or minocycline plus EDTA were shown to be as effective as broader-spectrum regimens.³²

In addition, catheter lock solutions were more effective when supplementary preventative measures like nasal decontamination with mupirocin and iodine dressing at the exit site were used. Antibiotic-free catheter lock solutions, mainly citrate, with heparin, also showed highly effective results when used in combination with topical antimicrobials and nasal mupirocin.³²

Although antibiotic ointments and antibiotic lock solutions are both effective in reducing the rate of bacteremia, a randomized study of 141 catheters comparing the efficacy of dressing the exit site with antibiotic ointment versus catheter antimicrobial locking, the ABL was proven to be markedly superior as a preventative measure for CRB.³³ In a study done on catheter-related bacteremia in children on chronic hemodialysis, CRBs were cleared with systemic antibiotics (AB) and antibiotic locks (tPA-ABL) in 63/76 patients (83%). The researchers concluded that tPA-ABL can safely and effectively be used in management of CRB, increasing the probability of catheter survival and preserving the vascular access site. With the exception of polymicrobial CRB, they found there is no disadvantage in using tPA-ABL/AB over catheter exchange, as the infection-free survival and rate of recurrence were comparable.³⁴ Mirza Onder et al also found no episodes of metastatic infection, catheter malfunction from occlusion, or catheter breakdown during the course of tPA-ABL treatments.³⁴

Antibiotic Coating

Antibiotic-coated catheters have shown significant antimicrobial properties. Rifampin and minocycline coat both the internal and external lumens of the catheter. Results of a meta-analysis of randomized controlled trials using rifampin-impregnated catheters conclude that surface-treated catheters were safe and effective at

reducing catheter colonization and catheter-related bacteremia when compared with a standard untreated catheter.³⁵ In 2002, the Centers for Disease Control (CDC) published guidelines recommending that antimicrobial-coated catheters be used in populations in which the rate of infection exceeded 3.3 per 1000 catheter days. A recent comprehensive review of all published studies on catheter-related bloodstream infections between 1990 and 2005 recommended that “antibiotic-coated catheters are clinically effective and cost saving compared with either aseptic-coated or standard catheters.”³⁶ Overall, the majority of studies have documented strong results calling for the use of antibiotic-coated catheters. The problem does remain in addressing the longevity of these coatings, and also the potential for antibiotic resistance.

Antithrombotic Coating

One approach to limiting catheter-related thrombosis and resultant infection is the development of bonding of the surfaces of the catheters with thrombolytic agents, such as heparin or similar agents. There are at least two antithrombotic coatings available on tunneled, hemodialysis catheters – the Carmeda BioActive Surface (CBAS) coating on the Spire Biomedical[®] catheter (Spire Biomedical, Inc., Bedford, MA), and the Trillium Biosurface coating developed by BioInteractions Ltd. (Redding, UK), available on the Covidien Tal Palindrome Emerald[®] catheter (Covidien, Norwalk, CT). Both of these surfaces use a heparin bonding to the catheter as an anticoagulant. Heparin works as a strong anticoagulant and can reduce thrombin-activated factors and the proliferation of smooth muscle cells.³⁷ Heparin-coated catheters have the potential to reduce biofilm and fibrin sheath formation as well as infection and thrombus formation. A recent retrospective comparison of heparin-coated and noncoated tunneled catheters was performed by Jain et al.³⁸ Results demonstrate blood flow rates at 30, 60, and 90 days to be slightly higher than in the coated catheters, but this rate was only 8%. Fewer CRBs were noted in the heparin-coated group. But there was no significant difference in catheters requiring exchange.

The Tal Palindrome Emerald[®] catheter also uses heparin bonding, but it is structured differently. It holds water at the catheter surface and repels blood cells by using a polyethylene oxide layer with negatively charged sulfate polymers. This combination minimizes the interaction between the catheter surface and the bloodstream, preventing cell deposition on the catheter surface. Heparin is covalently bonded to the polyethylene oxide layer for anticoagulation. In clinical trials on other implanted devices, this surface treatment has reduced platelet, complement, and granulocyte activation. These catheters are available today; however, the effects of these coatings need to be further evaluated in

the hemodialysis population to justify the increased cost. On average, an antimicrobial-treated nontunneled dialysis catheter costs about \$20 more than an uncoated catheter and a tunneled catheter with surface heparinization costs ~\$100 more than a standard catheter. Furthermore, more long-term trials need to be performed to assess the longevity of these coatings and to definitely document the safety of these catheters in individuals who may be HIT (heparin-induced thrombocytopenia) positive.

DIALYSIS CATHETER TIP DESIGN

The dialysis catheter market has also expounded recently on its latest catheter tip designs to improve and extend catheter functionality and decrease the rate of complications. Current hemodialysis machines require high blood flow rates in the range of 350 mL/min, to achieve adequate and consistent hemodialysis.¹⁰ According to the Dialysis Outcomes Quality Initiative (DOQI), a minimum flow rate of 300 mL/min is the minimum requirement; current dialysis catheters have been averaging in the vicinity of this number.³⁹ The initial catheter tip technology evolved from the market of two distinct and separate catheters (i.e., Tesio[®] catheter, Medcomp, Harleysville, PA) to the two distinct circular lumens staggered or step tip design (PermCath[®]; Covidien), to a single catheter with partially attached distinct catheter tips (i.e., Ash-Split catheter[®]; Medcomp).

For efficient dialysis, it also important to achieve high, reliable consistent blood flow without significant recirculation. Reversal of lumens is performed in patients with chronic dialysis catheters to correct inadequate inflow, usually created through the arterial lumen. However, this reversal is what creates recirculation problems. Recirculation is defined as the reentry of dialyzed blood from the venous return into the arterial inflow; this can reduce the efficiency of dialysis sessions in patients and lead to adverse effects.^{40,41} The staggered or step tip design is preferable to preventing recirculation.⁴²

The staggered tip design consists of an outflow lumen that extends several centimeters, usually 2.5 cm, below the level of the inflow tip. This design is thought to prevent recirculation. The initial Ash-split[®] catheter tip design (Medcomp) was thought to allow for higher flow rates, as it essentially functions as two separate catheters, similar to the Tesio[®] catheter. However, O'Dwyer et al⁴³ demonstrated no significant differences in blood flow rates in comparing the split tip catheter to the PermCath[®] (Covidien).⁴² The authors also suggested that the split tip design was more prone to kinking and had a higher rate of minor complications. A small study done by Van Ha et al⁴³ looked at a direct comparison between a split tip design catheter (Hemosplit[®]; Bard Peripheral Vascular, Tempe, AZ) versus nonsplit tip design (Vaxcel[®]; Boston Scientific, Inc., Natick, MA) and showed the split

catheter to have longer survival and less complication rates. However, this study was a retrospective design and did not measure flow rates.⁴³

The initial Ash-split[®] catheter tip was also designed with multiple sideholes cut along its catheter tips. These side holes were thought to allow for more inflow should the tips themselves thrombose from clot formation. The theory behind this was “more holes, more circulation, and less stasis.” However, the creation of these sideholes can also serve as a deterrent such that these holes can have irregular cut surfaces and therefore increase the chance of occlusion and dysfunction.⁹ Tal et al⁴⁴ recently compared two dialysis catheters, with and without side holes. Their results showed reduced bacteremia in the non-side hole catheters. The split tip design catheters may also cause endothelial damage to the nearby vessel lumen through movement of the split tips thereby allowing the formation of thrombus attached to the wall of the vessel. Another theory is that the presence of side holes does not allow heparin to stay within the lumen of the catheter tip, thereby also allowing for clot formation.⁴⁵

Given the continued evolving technology in the arena of creating the ideal catheter tip design, a summary of the more recent tip designs in the current market are outlined below.

Duraflow[®]

The Duraflow[®] (Angiodynamics) catheter is characterized by its hydro-tip design, which involves a reverse-tapered staggered tip design such that the arterial lumen is directed superiorly so as not to allow flow to stagnate in the direction of the placed catheter (Fig. 1). The hydro tip and reverse taper help to keep the catheter patent as it bumps up against the vessel wall or any other position. This, in turn, allows for greater flow rates regardless of the tip position. This can lead to a lower chance of occlusion even over long periods, and minimal venous backpressure. Other traditional step tip catheters have a straight edge on the arterial lumen, and may be more susceptible to these issues. When resting up against the vessel wall, traditional step tip design catheters do not have anything present to help prevent the opening from being either completely or at least partially blocked off.

NextStep[®]

The NextStep[®] (Arrow International, Inc., Reading, PA) catheter tip design is such that the catheter ports are reversed, with the venous port positioned in the superior vena cava, 8 cm above the location of the arterial port, which is positioned within the lower third of the right atrium. This allows for arterial lumen to be oriented directly within the atrial blood pool allowing for max-

Figure 1 (A) Hydrotip catheter design of the Duraflow[®] dialysis catheter. (Courtesy of Angiodynamics.) (B) Demonstration of placement over the wire. Note how the arterial lumen is oriented superiorly (arrow). (Courtesy of Angiodynamics.)

imal dilution of returned blood, thereby reducing recirculation (Fig. 2). Ross⁴⁶ performed a small prospective clinical study involving 10 hemodialysis patients showing positive results with baseline recirculation rates of 1.1% and at one month, 0% recirculation. The limitation of this study was the fairly small sample size.⁴⁶

Cannon II[®]

The Cannon II[®] (Arrow International, Inc.) catheter was designed to capitalize on the importance of the “ideal” location of the catheter tip. Because proper catheter tip positioning is critical for achieving optimal blood flow rates, this catheter was constructed such that the tip is placed first and then tunneled backward into the skin entry site. Optimal positioning of the catheter tip can be at times difficult to achieve with conventional antegrade technique; therefore, this catheter offers operators the chance to optimally place the tip prior to tunneling and offer optimal positioning of the cuff and exit site as well. A retrospective study performed by Davanzo et al looked at the efficacy and safety of this catheter and demonstrated no occurrences of catheter thrombosis or fibrin sheath formation over a 6-month period.⁴⁷ Ross et al have argued the importance of the ideal tunnel pathway, which can reduce catheter kinking

A

B

Figure 2 (A) Widely separated reversed tip catheter design of the NextStep[®] dialysis catheter. Note the characteristic widely separated lumens in this catheter. (Courtesy of Arrow International.) (B) Note the reversal of lumens. The arterial lumen draws blood from the right atrium (red arrows), while the superiorly placed venous lumen is positioned in the SVC (blue arrows). (Courtesy of Arrow International.)

along its course.⁴⁶ The retrograde tunneling approach has the benefit of not allowing the dilator or cuff to pass through the skin exit site, thereby offering the possibility of a tight seal at the tunnel entry site. The authors argue that this tight fit might aid in the decrease of infection. Again, further prospective randomized controlled trials need to be performed such to analyze the long-term benefits and consistency of this catheter.

Hemostream[®]

The Hemostream[®] (Angiotech Pharmaceuticals, Inc., Vancouver, Canada) catheter tip design is based on its

A

B

Figure 3 (A) Close end-on view of the characteristic set of three independent arterial lumen of the Hemostream[®] catheter. (Courtesy of Angiotech.) (B) View of how blood flow can be directed separately into the distinct arterial lumens, thereby offering the possibility of bypassing an occluded lumen if need be. (Courtesy of Angiotech.)

360-degree arterial tip configuration, allowing for elimination of the catheter side-walling against the nearby vessel. This particular patented design also features three independent arterial lumens, thereby ensuring good functional flow rates, even when two lumens are completely occluded (Fig. 3). This particular catheter was also uniquely designed such that the 360-degree arterial tip configuration can be placed via an “over-the-wire” insertion, without the need for a peel-away sheath. This theoretically allows for the catheter to be smoothly positioned over the wire, centralize itself in the appropriate position within the SVC/right atrial junction, without the traumatic insertion of the peel away sheath.

Tal Palindrome[®]

The Tal Palindrome[®] (Covidien) catheter tip design is composed of a symmetrical spiral end tip, such that the inflow occurs through the proximal part of the end hole, located 1 cm away from the catheter tip, and the outflow is a “jet” directed away from the catheter tip (Fig. 4).⁴⁸ This spiral tip is thought to allow reversal of dialysis lines during dialysis without the problem of recirculation.

Figure 4 (A) Symmetrical spiral “Z-tip” design of the Tal Palindrome[®] catheter. (Courtesy of Covidien.) (B) Demonstration of how flow is directed through the side slots and exiting through the tip (*arrows*). (Courtesy of Covidien.)

Spector et al recently investigated retrospectively the clinical outcome of the Palindrome[®] catheter in a sample of 85 patients.⁴⁹ Their results found the Palindrome[®] catheter to have a lower rate of complications, including infection and catheter malfunction. The rate of catheter malfunction was 17.4%. Ten of the 115 catheters placed (8.7%) were attributed to fibrin sheath formation. This fibrin sheath formation is a lower overall rate than that previously shown by other authors (i.e., 42–100%).

Spector et al propose that because the blood enters through the side slots and exits through the tip, this reduces the formation of thrombus around the tip, thereby reducing complications of infection and fibrin sheath formation.⁴⁹

SUMMARY

Although the ideal catheter has yet to be developed, strides have been made in dialysis catheter technology within the past decade. Given the increase in patients that are using hemodialysis catheters, up from 13% in the past decade,^{50,51} catheter development is taking on an increasingly important role. As Tal and Ni⁹ have stated, the most important feature in consideration of a particular catheter is not the ease of insertion or cost of the catheter, but rather its long-term functionality and overall low complication rate. Only a summary of a handful of dialysis catheters have been described in this review; nevertheless, there exists a plethora of available evolving dialysis catheters and each may have its unique characteristic design strengths. However, perhaps even more important is the need for nonbiased randomized controlled trials to evaluate these catheters and assess for catheter longevity and limiting complications. These randomized controlled trials can only aid future developers to focus on the particular details that may lead to better catheters. In the interim, it is important to remember that chronic dialysis catheters are inferior to and are not a substitute for creation of an arteriovenous fistula as the preferred long-term vascular access for dialysis.

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