

Clinical Outcome of the Tal Palindrome Chronic Hemodialysis Catheter: Single Institution Experience

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PURPOSE: To report the authors' clinical experience with the Tal Palindrome chronic dialysis catheter with a symmetric tip.

MATERIALS AND METHODS: During a 39-month period, 126 Palindrome catheters were placed consecutively in 85 patients. Follow-up was available for 115 catheters. Insertion complications, patency, catheter-related bacteremia, exit site infections, and reasons for catheter removal were recorded. The patient's initial cause of end-stage renal disease, underlying diseases, and site of access were recorded as well.

RESULTS: Patient ranged in age from 35 to 91 years (median, 69 years). Fifty percent of patients had diabetes. One hundred twenty-six Palindrome catheters were placed for a total of 12,046 catheter-days. The technical success rate of catheter placement was 100%. The average catheter indwell time was 105 days (range, 1–673 days). Catheters were inserted via the right ($n = 107$) or left ($n = 19$) jugular vein in all patients without insertional complication. Catheter-related infections occurred in 16 of the 115 catheters (13.9%) during the study period and culture-proved bacteremia occurred in four (3.5%). Seven exit site infections were recorded, and 10 catheters (8.7%) developed fibrin sheaths that necessitated catheter exchanges.

CONCLUSIONS: Clinical experience with the Tal Palindrome hemodialysis catheter demonstrated safe and reliable use with low infection rates.

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Tunneled hemodialysis catheters are an important temporary means of vascular access for patients requiring long-term hemodialysis, those awaiting renal transplantation, and those whose peritoneal or arteriovenous dialysis accesses are currently maturing or nonfunctional (1). Ideally, dialysis catheters should be considered a

bridge to permanent access. However, tunneled hemodialysis catheters often serve as permanent access for patients who have exhausted other access options (2,3).

The National Kidney Foundation–Dialysis Outcomes Quality Initiative Vascular Access Guidelines recommendation is that less than 10% of chronic hemodialysis patients would be dependent of catheters as their permanent chronic dialysis access (4). However, data show that 21% of all chronic dialysis population in the United States is maintained on dialysis catheters as their sole access (5). Hemodialysis catheters are commonly associated with complications that include thrombosis, infection, and fibrin sheath formation (6). These complications have a profound effect on hemodialysis patient's lives.

Commonly used long-term hemodialysis catheters have either a staggered tip design, meaning that the outflow tip extends several centimeters beyond the inflow tip, or the split-tip or dual catheter design. The Tal Palindrome (Covidien, Mansfield, Massachusetts) has a symmetric tip design that allows reversal of the dialysis lines during dialysis with reduced risk of recirculation (Fig 1) (7). The design of the Tal Palindrome catheter is such that the inflow is through the most proximal part of the spiral end hole, about a centimeter proximal to the catheter tip as well as from the side slot about 2 cm proximal to the tip. The outflow jet is directed away from the catheter tip, which prevents mixing with the inflow blood and thus reduces recirculation. In addition, the tip design and the shape of the side

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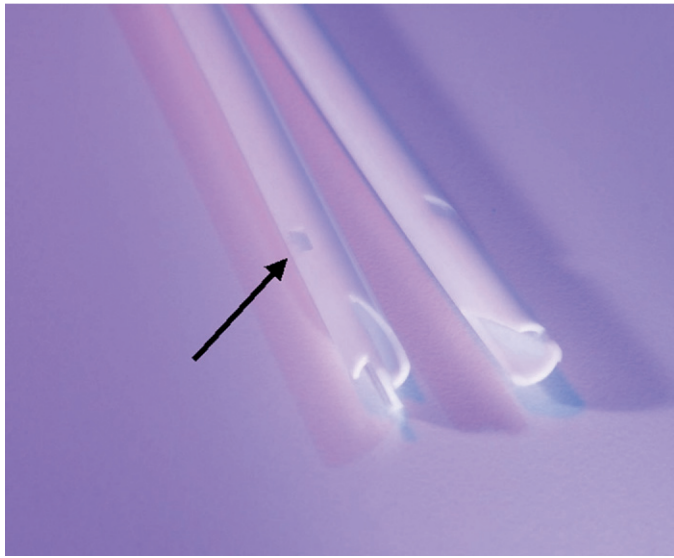


Figure 1. Tip of the Tal Palindrome catheter demonstrates a symmetric tip with a Z-shape design. Notice the side slots (arrow). (Image courtesy of Covidien.) (Available in color online at www.jvir.org.)

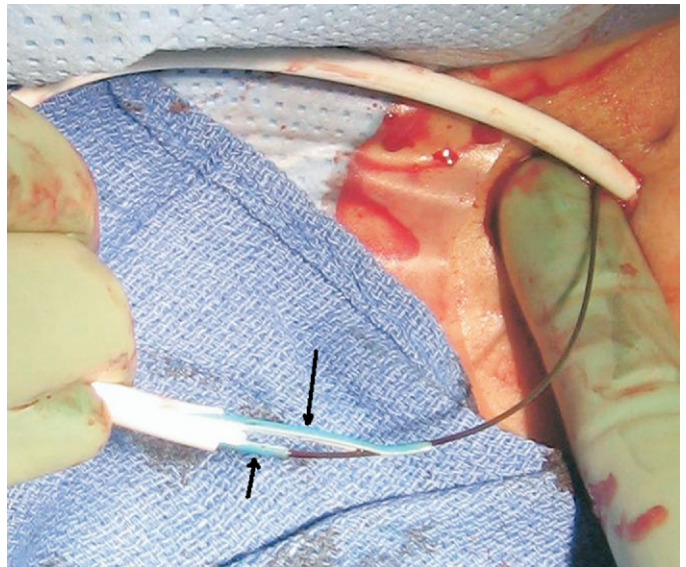


Figure 2. Image of the VenaTrac device. The device allows over-the-wire placement and exchange of the catheter. The VenaTrac consists of two D-shaped, blue stylets (arrows). The wire is passed through the tip of the long stylet (long arrow), into the short stylet (short arrow), and out the back end of the catheter. (Available in color online at www.jvir.org.)

slots allow for continuous self flushing of the catheter tip between treatments, with the intent of reducing thrombosis. The hypothesis behind the development of this catheter was that, in addition to reducing recirculation, it will reduce catheter-related complications (eg, fibrin sheath and infection) by reducing thrombosis. Herein, we describe a single institution's clinical outcome and clinical experience with this symmetric tip dialysis catheter.

MATERIALS AND METHODS

Patient Population

A retrospective review of all Tal Palindrome tunneled hemodialysis catheters that were placed, exchanged, or removed between May 3, 2004, and September 5, 2007 (39 months) was performed. During the study period, Palindrome was the main catheter used in our institution. In addition, 15 staggered-tip catheters and six split-tip catheters were placed during the transition period. The number of these catheters was too small to be included in this analysis. Patient demographics, catheter dwell time, insertion site, complications, and indications for removal were obtained. Institutional review board approval was obtained for this study.

Catheter Placements, Removals, and Exchanges

All procedures were performed by an experienced interventional radiologist (M.S., M.G.T., H.M., J.S.P., E.R., M.A.) in the interventional radiology suite. No antibiotics were administered during catheter placement. The study catheters were placed or exchanged in consecutive patients during the study period.

Access to the internal jugular vein was achieved under ultrasonographic guidance by using a lateral approach. Access was preferably made to the right internal jugular vein. Alternative access sites were used when the right jugular vein was thrombosed. Insertion of the Tal Palindrome catheter was performed either by using the provided valved peel-away sheath or over-the-wire using the VenaTrac device (Fig 2). The VenaTrac device is comprised of two D-shaped stylets that effectively occlude both lumens of the dialysis catheter, thus preventing air embolism or bleeding during over-the-wire catheter insertion or exchange. One stylet of the VenaTrac is longer than the other. The wire is passed through the tip of the longer stylet and into the shorter one. This allows catheter insertion or exchange

over a single wire by providing transition to the catheter tip. The VenaTrac was used for catheter exchanges. For exchanges, the catheters were bluntly dissected from the tunnel and retracted to the brachiocephalic vein. Injection of contrast medium was then performed with digital subtraction imaging over the chest. The presence of a fibrin sheath or thrombus was recorded. A new similar catheter was then inserted over one stiff 0.035-inch hydrophilic guide wire (Terumo Medical, Somerset, New Jersey) with the VenaTrac device. The new catheter was advanced under fluoroscopic guidance. Catheters were placed such that the tip was positioned in the upper right atrium.

Indications for catheter removal or exchange included poor function, infection, cuff exposure, maturation of an arteriovenous fistula or graft, resolution of the acute renal disease, and death. Poor catheter function was defined as a dialysis flow rate of less than 300 mL per minute.

The management of the fibrin sheath was variable and changed over time in our institution. At the beginning of the study, some operators performed fibrin sheath disruption with a 12-mm angioplasty balloon. Over

time, this practice has changed and most fibrin sheaths in the study were managed with simple catheter exchange over the wire by using the VenaTrac device.

In patients with clinical signs of infection, catheters were removed without venography and the tip was sent for culture and sensitivity. The treatment of catheter-related infection in our institution is variable; however, catheter removal is usually performed immediately without an attempt for antibiotic treatment and catheter salvage. A new catheter is then inserted after the symptoms have resolved and the blood cultures are negative.

Data Recording

Data were collected prospectively in the interventional radiology suite. Every chronic tunneled dialysis catheter placed was entered into an Excel database (Microsoft, Seattle, Washington). Follow-up was performed during follow-up visits and with computerized patient charts, which are available for all patients in our institution. The computerized patient charts allowed access to all notes, laboratory results, and imaging studies. Data analysis was performed at the end of the study period.

Study End Points

Patients were followed up until the removal of their hemodialysis catheters. The study end point was catheter removal.

Rates of occurrence of all complications and infections were calculated by dividing the number of catheters removed for that reason(s) by total indwelling time of all catheters. This was expressed as occurrence per 1,000 catheter days.

RESULTS

A total of 126 Tal Palindrome catheters were placed in 85 patients during the study. There were 84 men and one woman aged 35–91 years (median, 69 years). Hypertension was present in 72 of the 85 patients (85%) and diabetes was present in 43 (50%).

Most catheters (104, 82.5%) were placed from the right internal jugular vein, followed by the left internal jugular vein (18 catheters, 14.3%), right ex-

ternal jugular (three catheters, 2.3%), and left external jugular (one catheter, 1%). No subclavian or femoral access was performed during the study period. Eighty-five of the 126 catheters (67.5%) were primary placements and 41 (32.5%) were catheter exchanges. No insertional complications were recorded during the study, and the technical success of catheter insertion was 100%.

Follow-up information, including the reason for removal (**Table**) and dwell time, was available for 115 of the 126 catheters (91.2%). Dwell time ranged from 1 to 673 days, for a total of 12,046 catheter-days (median, 73 days; average, 105 days). The most common indication for removal or termination of the use of the catheter was the presence of a mature access, usually a functioning fistula. This occurred in 29 of the 115 catheters (25.2%). Twelve additional catheters (10.4%) were removed because they were no longer needed. Only 16 catheters (13.9%) were removed due to clinical signs of infection. The total infection rate was 1.4 per 1,000 catheter-days. Of those, only four of the 115 catheters (3.5%) demonstrated proven catheter-related bacteremia, with a bacteremia rate of 0.3 per 1,000 catheter-days. Seven exit site infections were recorded, and five catheters were removed because of clinical suspicion for infection, with negative blood cultures and negative catheter tip cultures.

Fibrin sheath was deemed as the reason for exchange in 10 of the 115 catheters (8.7%). Ten catheters were exchanged due to poor flow, with no fibrin sheath visualized at venography. Nineteen patients (22%) died during the study of unrelated causes while having a functioning catheter.

The total complication rate was 3.65 per 1,000 catheter-days, of which 1.3 complications per 1,000 catheter-days were due to infection and 1.7 were due to catheter malfunction. The other 0.65 complications per 1,000 catheter-days were due to catheter retraction and thrombus formation that could be also be considered as catheter malfunctional.

Of the 126 catheters placed, only three are still in patients, with the dwell time for those catheters ranging from 135 to 286 days.

Indications for Catheter Removal or Exchange

Indication	No. of Catheters (n = 115)*
Functioning fistula/graft	29 (25.2)
Catheter not needed	12 (10.4)
Peritoneal dialysis	4 (3.4)
Infection	16 (13.9)
Fibrin sheath	10 (8.7)
Poor flow	10 (8.7)
Retracted catheter	5 (4.3)
Thrombus formation	3 (2.6)
Other	3 (2.6)

Note.—19 patients died during the study with a functioning catheter. Three catheters are still functioning. * Follow-up data were available for 115 catheters. Numbers in parentheses are percentages.

DISCUSSION

Tunneled hemodialysis catheters are not desirable but are an essential tool for providing dialysis access. A substantial part of the dialysis patient population rely on these catheters for access (4). Catheter complications are common and dialysis catheter outcomes are generally poor. In a recent article by Alomari and Falk (6), outcome of standard dialysis catheters showed that about a third were removed or exchanged for infection, a third for nonfunction, and a third for being no longer needed.

In this review of the natural history of 126 symmetric tip Tal Palindrome tunneled hemodialysis catheters, the most common complications were infection (13.9%) and catheter malfunction (17.4%). These complications rates are lower than previously reported in the literature. Later in this discussion, we will try to inquire into the possible reasons for this difference.

Sixteen (13.9%) catheters were removed for clinically evident infection. This frequency is lower than what is described in similar studies using standard catheters. In a prospective analysis of outcome of 118 AshSplit (Medcomp, Harleysville, Pennsylvania) hemodialysis catheters, Ewing et al (8) demonstrated that 34% were removed for infection. Marr et al (9) reported on 102 patients (with a total of 16,081 catheter days), of whom 41 (40%) developed 62 episodes of bacte-

remia. Cheesbrough et al (10) reviewed 74 subclavian hemodialysis catheters inserted into 53 patients. Sixteen of 64 catheters with follow-up were complicated by clinically documented catheter-related sepsis (10). Similar results were reported by Capdevila et al (11) with 36 Permcath (Sherwood Medical, St Louis, Missouri) double-lumen catheters implanted in 36 patients with chronic renal failure, 11 of whom had 13 episodes of catheter-related sepsis.

The rate of catheter-related infection in our cohort of patients was 1.3 per 1,000 catheter-days. The rate of this complication reported in the literature is variable and dependent on the definition of a catheter-related infection. In a large review by Saad (12), bacteremia rates of 2.2–5.5 per 1,000 catheter-days were reported.

The indication for catheter exchange at our institution is a catheter flow rate of less than 300 mL/min, which is similar to that described by Alomari and Falk (6). According to the National Kidney Foundation–Dialysis Outcomes Quality Initiative guidelines (13), a definition of poorly functioning hemodialysis catheters is a blood flow of less than or equal to 300 mL/min.

In our study, 20 catheters (17.4%) were exchanged for poor function, 10 of them (8.7%) due to fibrin sheath. Catheter malfunction in our series was 1.7 per 1,000 catheter-days. Catheter exchange is an important procedure in that it allows conservation of other central venous access sites for future use. Over-the-wire catheter exchange through preexisting subcutaneous tunnels has been shown to be safe and easily performed. In our series, the VenaTrac device (Fig 2) was used for catheter exchange. Use of the VenaTrac in this study showed no complications and no incidence of air embolism.

Fibrin sheath formation is reported to occur in 42%–100% of central venous catheters (13). Our series reports a lower fibrin sheath rate (10/115, 8.7%) than that reported by other authors, which was approximately 50% (14–16). Granted, pull-back venography was not performed in all patients in our study, only those with malfunctioning catheters, which might underestimate the true incidence of fibrin sheath.

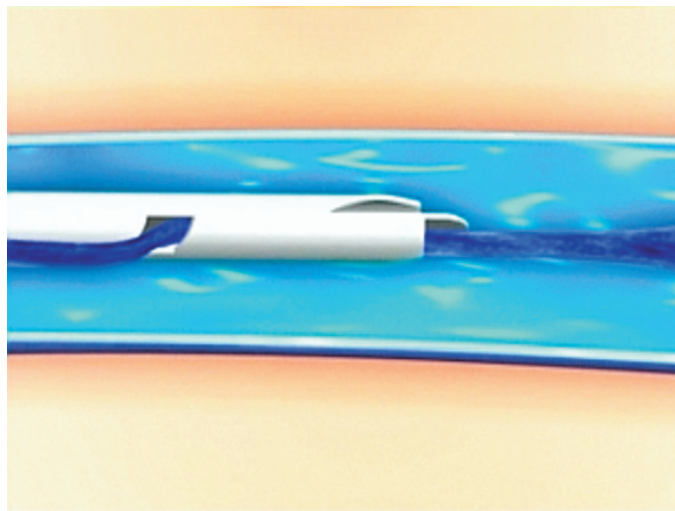


Figure 3. Illustration of the presumed self-flushing of the catheter between dialysis treatments. Blood goes through the laser-cut side slot and out the catheter tip. (Image courtesy of Covidien.) (Available in color online at www.jvir.org.)

Fibrin sheaths are reported to be the most common cause of tunneled hemodialysis access catheter failure (6). Fibrin sheath formation starts almost immediately and can be seen as early as 24 hours after catheterization; encasement of the catheter can be seen within a week (17). The fibrin sheath begins where the catheter contacts the vein wall and is formed by smooth muscle cells and endothelial cell migrating from the injured vein wall into the pericatheter thrombus (18). Chronic dialysis catheters display vein wall thickening and extension of the fibrin sheath from the vein wall to the catheter (19). It has been shown that fibrin sheaths and associated thrombi provide an intravascular medium for bacterial colonization and sepsis (20,21). This association of fibrin sheaths with venous thrombosis and bacterial contamination adversely affects the longevity of hemodialysis catheters.

That known association among thrombosis, fibrin sheath, and infection can possibly explain the improved results seen in our series. The Tal Palindrome design theoretically allows flow of blood through the catheter tip between treatments. The blood enters through the side slots and exits through the tip (Fig 3). This flow of blood might reduce thrombus formation on the catheter tip, thus reducing the associated complications of infection and fibrin sheath. Another unique feature of the Tal Palindrome catheter

is the lack of side holes. Studies have proposed that side holes are detrimental to dialysis catheter functions (22). One study (23) comparing identical dialysis catheters with and without side holes showed a reduced infection rate in the catheters without side holes. The explanation for the discrepancy in infection rates in that study was that the catheters without side holes had lower catheter tip thrombus formation and, thus, lower infection rates. This same rationale can explain the improved outcomes with the catheter studied in our series. The Tal Palindrome catheter has one laser-cut side slot per lumen. This side slot is in the shape of a parallelogram (Fig 1). The laser cutting process melts the edges of the catheter during the cutting process and, hence, the edges of the side slot are smooth. These side slots might reduce the catheter tip thrombosis and associated fibrin sheath and infection. The properties of this side slot compared to the multiple side holes present in the other catheters evaluated in the literature could help explain the difference in complication rates.

Limitations of our study include a nonrandomized sample, single institution study, retrospective nature of the study, and the lack of a control group. No statistical analysis for significance of these findings could be performed because there was no control group. Due to the nature of our hospital pop-

ulation, all but one of the patients in this study was male.

In conclusion, we found that, in comparison with previously published studies, the Tal Palindrome catheter has a lower rate of complications, including infection and catheter malfunction. Randomized controlled studies are needed to directly compare this catheter to other catheters to validate these findings.

References

- Schwab SJ, Beathard G. The hemodialysis catheter conundrum: hate living with them, but can't live without them. *Kidney Int* 1999; 56:1-17.
- Trerotola SO. Hemodialysis catheter placement and management. *Radiology* 2000; 215:651-658.
- Dialysis Outcomes Quality Initiative. (DOQI). National Kidney Foundation. Clinical Practice Guidelines for Vascular Access. Guideline 37—Cumulative patency rate of tunneled cuffed catheters. Available at <http://www.kidney.org/professionals/doqi/doqi/vag37.html>. Last accessed 5/1/08.
- Dialysis Outcomes Quality Initiative. (DOQI). National Kidney Foundation. Clinical Practice Guidelines for Vascular Access. Guideline 30—Goals of Access Placement—Use of Catheters for Chronic Dialysis. Available at <http://www.kidney.org/professionals/doqi/doqi/vag30.html>. Last accessed 5/1/08.
- Summary Report of the End State Renal Disease Networks Annual Report 2003. Available at <http://www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/NetworkAnnualReport2003.pdf>. Last accessed 5/1/08.
- Alomari AI, Falk A. The natural history of tunneled hemodialysis catheters removed or exchanged: a single institution experience. *J Vasc Interv Radiol* 2007; 18:227-235.
- Tal M. Comparison of recirculation percentage of the Palindrome catheter and standard hemodialysis catheters in a swine model. *J Vasc Interv Radiol* 2005; 16:1237-1240.
- Ewing F, Patel D, Petherick A, Winney R, McBride K. Radiological placement of the AshSplit haemodialysis catheter: a prospective analysis of outcome and complications. *Nephrol Dial Transplant* 2002; 17:614-619.
- Marr KA, Sexton DJ, Conlon PJ, Corey GR, Schwab SJ, Kirkland KB. Catheter-related bacteremia and outcome of attempted catheter salvage in patients undergoing hemodialysis. *Ann Intern Med* 1997; 127:275-280.
- Cheesbrough JS, Finch RG, Burden RP. A prospective study of the mechanisms of infection associated with hemodialysis catheters. *J Infect Dis* 1986; 154:579-589.
- Capdevila JA, Segarra A, Planes AM, et al. Successful treatment of haemodialysis catheter-related sepsis without catheter removal. *Nephrol Dial Transplant* 1993; 8:231-234.
- Saad TF. Central venous dialysis catheters: catheter-associated infection. *Semin Dial* 2001; 14:446-451.
- Dialysis Outcomes Quality Initiative. (DOQI). National Kidney Foundation. Clinical Practice Guidelines for Vascular Access. Guideline 23—Treatment of Tunneled Cuffed Catheter Dysfunction. Available at http://www.kidney.org/professionals/kdoqi/guidelines_updates/doqiupva_v.html#23. Last accessed 5/1/08.
- Cassidy FP Jr, Zajko AB, Bron KM, Reilly JJ Jr, Peitzman AB, Steed DL. Noninfectious complications of long-term central venous catheters: radiologic evaluation and management. *Am J Roentgenol* 1987; 149:671-675.
- Oguzkurt L, Tercan F, Torun D, Yildirim T, Zumurtdal A, Kizilkilic O. Impact of short-term hemodialysis catheters on the central veins: a catheter venographic study. *Eur J Radiol* 2004; 52:293-299.
- Beathard GA. Dysfunction of new catheters by old fibrin sheaths. *Semin Dial* 2004; 17:243-244.
- Hoshal VL, Aulsebrook RG, Hoskins PA. Fibrin sleeve formation on indwelling subclavian central venous catheters. *Arch Surg* 1971; 102:353-358.
- Xiang DZ, Verbeken EK, Van Lommel AT, Stas M, De Wever I. Composition and formation of the sleeve enveloping a central venous catheter. *J Vasc Surg* 1998; 28:260-271.
- Forauer AR, Theoharis C. Histologic changes in the human vein wall adjacent to indwelling central venous catheters. *J Vasc Interv Radiol* 2003; 14:1163-1168.
- Raad II, Luna M, Khalil SA, Costerton JW, Lam C, Bodey GP. The relationship between the thrombotic and infectious complications of central venous catheters. *JAMA* 1994; 271:1014-1016.
- Timsit JF, Farkas JC, Boyer JM, et al. Central vein catheter-related thrombosis in intensive care patients: incidence, risk factors, and relationship with catheter-related sepsis. *Chest* 1998; 114:207-213.
- Twardowski ZJ, Moore HL. Side holes at the tip of chronic hemodialysis catheters are harmful. *J Vasc Access* 2001; 2:8-16.
- Tal MG, Peixoto AJ, Crowley ST, et al. Comparison of side hole versus non side hole high flow hemodialysis catheters. *Hemodialysis Int* 2006; 10:63-67.