Clinical Studies

Effectiveness of a New Tunneled Catheter in Preventing Catheter Malfunction: A Comparative Study

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PURPOSE: To compare infection and malfunction rates of two different types of antimicrobial-eluting tunneled cuffed catheters (TCCs) for hemodialysis.

MATERIALS AND METHODS: The HemoSplit TCC with BioBloc (silver sulfadiazine) coating (n = 100, control group) and the Tal Palindrome Ruby TCC, which has a novel silver antimicrobial sleeve and a spiral-z tip design (n = 100, study group), were compared in this case-controlled study. The main endpoints were TCC infection and malfunction.

RESULTS: Primary-assisted TCC patency was significantly reduced with the BioBloc TCC (71% and 61% at 90 and 180 days, respectively) compared with the Palindrome Ruby TCC (94% at 90 and 180 days, $P < .0001$). Multivariate analysis identified only the BioBloc TCC and common femoral access site as independent predictors of worse patency. The unadjusted relative risk (95% confidence interval) for TCC dysfunction with the BioBloc compared with the Palindrome Ruby was 6.0 (2.33–15.53, $P < .001$), and the relative risk adjusted for access site was 3.2 (1.71–11.96, $P = .002$). The infection-free rates of the two TCC types were similar ($P = .36$). The reintervention-free rate for infection or malfunction was significantly better with the Palindrome Ruby TCC (76% and 58% at 90 and 180 days, respectively) than with the BioBloc TCC (60% and 45% at 90 and 180 days, respectively; $P = .03$).

CONCLUSIONS: The results support the use of the Palindrome Ruby TCC on the basis of the significantly lower thrombosis and reintervention rate; randomized trials are justified to confirm this finding and to evaluate its role in the prevention of TCC infection.

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Abbreviations: CI = confidence interval, MRSA = methicillin-resistant *Staphylococcus aureus*, TCC = tunneled cuffed catheter, VRE = vancomycin-resistant *Enterococcus*

THE National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines have repeatedly emphasized the importance of reducing the use of tunneled cuffed catheters (TCCs) for long-term renal replacement therapy because they are the cause of increased morbitity due to infection and malfunction (1,2). Despite the best efforts, some patients will rely on a TCC to get sufficient renal replacement therapy, either temporarily, during the process of getting a functional arteriovenous access (autogenous fistula or prosthetic graft), or indefinitely, because their vascular anatomy is not suitable for creating an arteriovenous access and assuming that they are not candidates for peritoneal dialysis or kidney transplantation. TCC malfunction (due to catheter thrombosis or development of a fibrin sheath) and infection (including involvement of the tunnel and/or its exit site) result into access site loss and, not infrequently, metastatic infection and death. Although research has improved the design of TCCs so that infection rate and catheter survival is improved (3–5), there is still an urgent need for further advances.

The aim of the current study was to compare infection and patency rates of two antimicrobial-eluting TCCs with different tip designs: the HemoSplit BioBloc TCC (Bard Access Systems, Salt Lake City, Utah) and the new Tal Palindrome Ruby TCC (Tyco Healthcare/Kendall, Mansfield, Massachusetts [now Covidien]). The primary hypothesis was that the modified antimicrobial-eluting technology and

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Table 1
Summary of Baseline Patient Demographics

Parameter	BioBloc TCC Group (n = 100)	Palindrome Ruby TCC Group (n = 100)	P Value
Median age (y)*	58.5 (50–78)	56 (49–65)	.22
Male sex	45 (45)	49 (49)	.57
Diabetes mellitus	44 (44)	56 (56)	.09
Catheter location			
Right internal jugular vein	50 (50)	68 (68)	.001
Left internal jugular vein	18 (18)	23 (23)	
Right common femoral vein	23 (23)	7 (7)	
Left common femoral vein	9 (9)	2 (2)	
TCC exchange procedure	51 (51)	32 (32)	
Indication			.006
Malfunction	29 (57)	18 (56)†	
Infection	13 (26)	14 (44)	.08
Conversion	8 (16)	0 (0)	
Broken catheter	1 (2)‡	0 (0)	
Concomitant angioplasty of fibrin sheath	6 (12)	1 (3)	.24
Infection around placement§	15 (15)	22 (22)	.20

Note.—Except where indicated, numbers in parentheses are percentages.
* Numbers in parentheses are the interquartile range.
† P = .067 for malfunction indication alone versus the rest.
‡ In a pre-existing BioBloc TCC.
§ Defined as any bacteremia during the last 3 weeks before new catheter placement (n = 19, all with negative interval blood cultures) or exchange for definite or probable catheter infection (n =18).

novel catheter tip design of the latter TCC would result in reduced infection and malfunction rates, respectively.

MATERIALS AND METHODS

Two hundred TCC placements in 163 patients with end-stage renal disease (ESRD) who were referred for new TCC placement or exchange of a pre-existing TCC over a guide wire between June 2006 and April 2007 are included in this retrospective study. The study was approved by the hospital institutional review board. One hundred catheter placements were performed with HemoSplit TCCs with BioBloc (silver sulfadiazine) coating (Bard Access Systems), referred to as BioBloc TCCs; these patients served as the control group. The remaining 100 placements were performed with Tal Palindrome Ruby TCCs (Tyco Healthcare/Kendall), referred as Palindrome Ruby TCCs; these patients served as the study group. The Palindrome Ruby TCC has a novel silver antimicrobial sleeve permanently bonded to the external surface of the catheter. For practical purposes, catheter placement was consecutive, because 91% of all BioBloc TCCs included in the present study were placed up to the end of October 2006, when we started using the Palindrome Ruby TCC. Patient demographics, indications for TCC placement, and catheter sites in the two groups are shown in **Table 1**.

The bacteriology results (obtained from blood and/or the catheter tip) indicative of infection around the time of TCC insertion are shown in **Table 2**. The following BioBloc TCC lengths were used: 19 cm (n = 21), 23 cm (n = 39), 27 cm (n = 8), 31 cm (n = 2), 35 cm (n = 24), and 42 cm (n = 6). The following Palindrome Ruby TCC catheter lengths were used: 19 cm (n =30), 23 cm (n = 40), 28 cm (n = 21), and 33 cm (n = 9).

TCC Description

Both catheter types, shown in **Figure 1**, use eluting technology, with the difference that the BioBloc TCC has a silver sulfadiazine coating applied to the external surface of the catheter between the hub and cuff and cuff to midcatheter, and the Palindrome Ruby TCC has a silver antimicrobial sleeve permanently bonded to the external surface of the catheter, between the hub and cuff. The BioBloc TCC has been shown in an in vitro 21-day adhesion model to reduce bacterial adhesion to the catheter by 99.9% in the catheter tunnel. The Palindrome Ruby TCC has been shown in an in vitro 30-day colonization model and an in vivo 30-day infection model to reduce the amount of microbial colonization on the silver-impregnated sleeve (6).

The BioBloc TCC has a split distal tip design, with the venous lumen extending beyond the arterial lumen. The two lumens are separated at a maximum of 8 cm proximal to the distal tip of the venous lumen and are able to float freely in the bloodstream; each lumen has two side holes. The TCC is made of soft polyurethane that contains barium sulphate in order to be radiopaque. The Palindrome Ruby TCC is a new bi-directional dialysis catheter with a novel symmetric spiral-z design tip that supports line reversal with a minimal incidence of recirculation (5). It also has laser-cut side slots, which are designed to promote flow over the catheter slot surface and lessen the risk for clot formation.

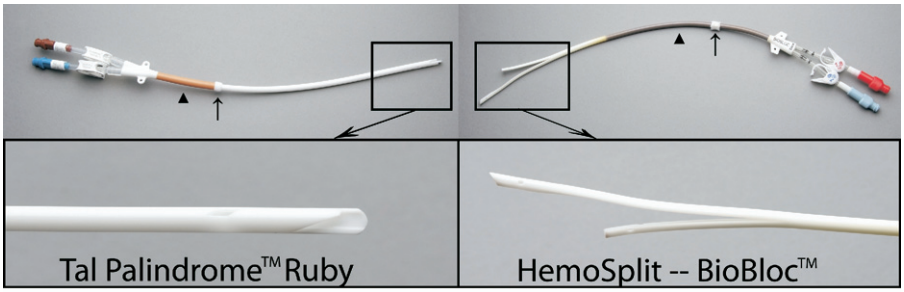
Follow-up and Management

All TCCs were followed up to the end of primary assisted patency (cath-

Table 2
Distribution of Events in the BioBloc and Palindrome Ruby Groups

Parameter	No. of Events		*P* Value	Odds Ratio*
	BioBloc TCC (n =100)	Palindrome Ruby TCC (n = 99)		
Thrombosis	32 (32%)	5 (5%)	<.001	0.11 (0.04–0.31)
No. per 1,000 catheter days	2.86	0.51		
Infection	18 (18%)	24 (24%)	.28	1.46 (0.73–2.90)
No. per 1,000 catheter days	1.61	2.46		
Reintervention for thrombosis or infection	50 (50%)	29 (29%)	.003	0.41 (0.23–0.74)
No. per 1,000 catheter days	4.48	2.97		
Exit site infection	1 (1%)	0 (0%)	1.00	NA
No. per 1,000 catheter days	0.09	0		
Tunnel infection	0 (0%)	1 (1%)	.50	NA
No. per 1,000 catheter days	0	0.10		
TCC site loss	9 (9%)	12 (12%)	.49	1.38 (0.55–3.43)
No. per 1,000 catheter days	0.81	1.23		

* Numbers in parentheses are the 95% CI. NA = not applicable.



a. **b.**

Figure 1. **(a)** Palindrome Ruby TCC. The catheter cuff (arrow), the hub-to-cuff silver-impregnated antimicrobial sleeve (arrowhead), and a close-up view of the TCC tip (symmetric spiral-z design tip, bottom part of the image) are shown. **(b)** BioBloc TCC. The catheter cuff (arrow), the hub-to-midcatheter silver sulfadiazine coating of the external surface of the catheter (arrowhead), and a close-up view of the TCC tip (split distal tip design, bottom part of the image) are shown. (Available in color online at *www.jvir.org*.)

eter removal or exchange for malfunction), infection (which prompted removal or exchange), or patient death. TCC use was monitored by the hemodialysis units that referred the patient back in case of TCC dysfunction that failed local thrombolysis. TCC infection was managed with patient admission to the hospital and catheter exchange or removal, according to the DOQI guidelines (1,2). Exchange over a guide wire was our favored technique for both TCC dysfunction (7) and infected TCCs that did not necessitate immediate removal (8). TCCs that were removed because of recovered renal function, functional vascular access, or kidney transplantation were followed-up to that point.

Description of TCC Placement Technique

TCCs were placed under local anesthesia (1% lidocaine), with optional monitored conscious sedation (midazolam and fentanyl), in a hospital-based interventional suite for both outpatients and inpatients. C-arm devices used were the BV Pulsera (Philips Medical Systems, NL B.V., Best, The Netherlands) and the OEC Series 9600 (OEC Medical Systems, Salt Lake City, Utah). The preferred insertion site was the right internal jugular vein, followed by the left internal jugular vein and common femoral veins. The insertion site was prepped and draped. With ultrasonographic (US) guidance (Site-Rite; Bard Access Systems), the selected vein was punctured with a 21-gauge needle with an echogenic tip and a 0.018-inch guide wire inserted (5-F Micro Access kit; Angiodynamics, Queensbury, New York) as previously described (9). The guide wire was advanced with fluoroscopic guidance to the right atrium (or inferior vena cava in case of a femoral catheter). This was followed by placement of a 5-F sheath and wire exchange for a 0.035-inch hydrophilic wire that was advanced under fluoroscopy well into the inferior vena cava, to avoid incidental dislocation to the heart that can cause arrhythmias. Then, two small incisions were made—one at the access site and the other at the intended exit site—and, by using a hemostat, we fashioned a subcutaneous tunnel. In the neck, we use the lateral tunneling technique, with the exit site being below the middle part of the clavicle (10). Then, the catheter was placed inside the tunnel with use of a tunneler, with its distal portion outside the entry site wound. The entry site was subsequently dilated with the TCC kit dilator(s) and a peel-away valved sheath placed—both with fluoroscopic guidance. Then, the catheter was inserted in its final position over the guide wire through the sheath that is split. In the case of internal jugular vein catheters, the final position is the right midatrium or the atrium–superior vena cava junction. In femoral TCC placements, the final position is the inferior

vena cava. This, again, was checked with fluoroscopy, which was also used to rule out catheter kinking. The catheter was then checked for free flow with a 10-mL syringe, flushed with normal saline, and locked with heparin solution (1,000 U/mL). The TCC was finally sutured in place and cleared for immediate hemodialysis, with chest radiography performed for those in the jugular site to rule out pneumothorax or hemothorax and confirm the final position of the tip, per hospital policy.

TCC exchange (for malfunction and/or thrombosis, infection in stable patients, and catheter dislodgement or breakdown) was performed over a 0.035-inch hydrophilic wire that was advanced under fluoroscopy to the inferior vena cava. This was followed by removal of the pre-existing TCC (after its cuff was freed under local anesthesia), cleansing of the guide wire with betadine and saline solution, and insertion of the new TCC, which was subsequently checked and treated like a new TCC (apart from chest radiography, see above). In the rare occasion of poor flow, as checked with the syringe, the catheter was withdrawn under fluroscopy for about 10 cm so that its tip was located in the superior vena cava. Then, contrast medium was injected to obtain a venogram to rule out the presence of a fibrin sheath, which would require balloon dilation. If the TCC was exchanged for infection in a stable patient, its tip was sent for culture; the catheter tip was not sent for culture if there was no suspicion for infection. Conversion of a nontunneled catheter to a TCC follows the same principles of a new placement, with the exception that access has already been established (11).

Infection Definition

Exit-site infection was defined as inflammation confined to the area surrounding the catheter exit site, not extending superiorly beyond the cuff, with exudate culture confirmed to be positive. *Tunnel infection* was defined as the catheter tunnel superior to the cuff being inflamed and painful and possible drainage through the exit site that is culture positive (2). For catheter-related infections, we used the Centers for Disease Control (CDC) definitions, as adopted by the KDOQI guidelines (2). *Definite bloodstream infection* was diagnosed if the same organism was found in a semiquantitative culture of the catheter tip (>15 colony-forming units per catheter segment) and from a peripheral or catheter blood sample in a symptomatic patient with no other apparent source of infection. *Probable bloodstream infection* was diagnosed with defervescence of symptoms after antibiotic therapy with or without removal of catheter, in the setting in which blood cultures confirm infection but culture of the catheter tip does not (or catheter tip does, but blood cultures do not) in a symptomatic patient with no other apparent source of infection. *Possible bloodstream infection* was diagnosed with defervescence of symptoms after antibiotic treatment or after removal of the catheter in the absence of laboratory confirmation of bloodstream infection in a symptomatic patient with no other apparent source of infection.

Statistics

All data were entered into a database (Microsoft Office Access 2003; Microsoft, Redmond, Washington) and analyzed with software (SPSS 14.0 for Windows; SPSS, Chicago, Illinois). Reporting Standards for Arterio-Venous Accesses of the Society for Vascular Surgery and the American Association for Vascular Surgery (12), and for Central Venous Access of the Society of Interventional Radiology (13) were used to define TCC and TCC site patency. TCC primary assisted patency was defined as a patent catheter without exchange or removal for malfunction; catheter primary infection-free survival was defined as a patent catheter without exchange or removal for infection. Additional life table analysis was performed for the combined endpoint of malfunction and infection. Secondary catheter site patency was defined as the interval from the time of placement until catheter site abandonment, completion of therapy, or time of measurement of patency—including catheter replacements (exchanges)—provided the access site is maintained.

TCC and TCC site survival were calculated with the Kaplan-Meier method and compared with the log-rank (Mantel-Cox) test. TCC infection and malfunction rates were also calculated as number per 1,000 catheter days. Multivariate analysis of the effect of clinical variables (eg, age; sex; diabetes mellitus; length, type, and location of TCC; indication for and type [new or exchange] of placement; presence of bacteremia around the time of placement) on patency and infection rates was performed with the Cox regression method (Forward and Backward Wald models). The Kolmogorov-Smirnov test was used to test numeric data for normal distribution; normally distributed data were compared with the t test, otherwise distribution-free test methods (Mann-Whitney test) were used. Categorical data were analyzed with the χ^2 or Fisher exact test where appropriate. A P value of less than or equal to .05 was considered statistically significant.

RESULTS

Complications and Technical Success

Fibrin sheath balloon angioplasty was performed in seven of 83 exchange procedures (8%). This was performed in a single case in which the Palindrome Ruby TCC (one of 51, 3%) was placed (with concomitant balloon dilation of a 50% innominate vein stenosis) and in six exchange procedures in which the BioBloc TCC was placed (six of 51, 12%, P = .24, with concomitant innominate vein balloon angioplasty in five of the six). One procedure (0.5%) was complicated with hemothorax; this occurred during conversion of a pre-existing right internal jugular vein nontunneled access site to a BioBloc TCC; the original procedure was performed at an outside facility. Initially, this was managed conservatively but subsequently necessitated lung decortication. Computed tomography (CT) demonstrated that the TCC entry site was low at the posterior wall of the innominate vein. Technical success was 99%; two BioBloc TCCs (2%) had to be exchanged after 24 hours because of malfunction related to the placement procedure. This did not occur with any of the Palindrome Ruby TCCs.

Follow-up

One of the 200 TCCs (0.5%) that had an uncomplicated and technically successful procedure was lost to follow-up, with the patient under-

going dialysis out of our catchment area. This was a Palindrome Ruby TCC. This left 199 TCCs in the study, with a total of 20,938 catheter days—11,173 for the BioBloc and 9,765 for the Palindrome Ruby. Patency and infection rates are shown in **Table 2**. During follow-up, 20 BioBloc TCCs were removed because they were not needed anymore owing to functioning arteriovenous access ($n = 9$), peritoneal dialysis ($n = 2$), and recovered renal function ($n = 5$). In four cases, there was an elective switch to the internal jugular vein site. Similarly, 19 Palindrome Ruby TCCs were removed because of functioning arteriovenous access ($n = 7$), peritoneal dialysis ($n = 2$), recovered renal function ($n = 7$), or kidney transplantation ($n = 2$). In addition, one BioBloc TCC and four Palindrome Ruby TCCs had to be removed because they were dislodged. One additional Palindrome Ruby TCC with cuff exposure was salvaged with an over-a-wire exchange.

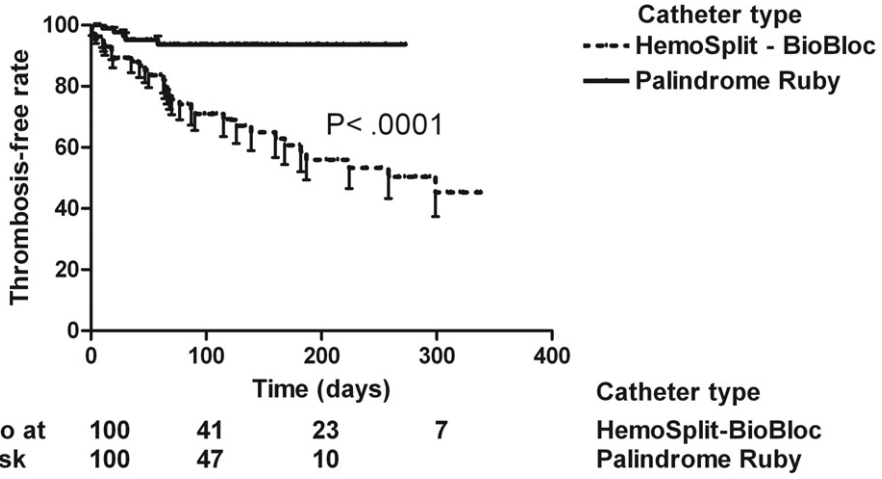


Figure 2. Graph shows the primary assisted patency of the BioBloc and Palindrome Ruby TCCs. The primary assisted patency of the Palindrome Ruby TCC was significantly greater than that of the BioBloc TCC ($P < .0001$). Error bars of the Kaplan-Meier survival curves represent the standard error; the number of patients at risk at each interval is also shown.

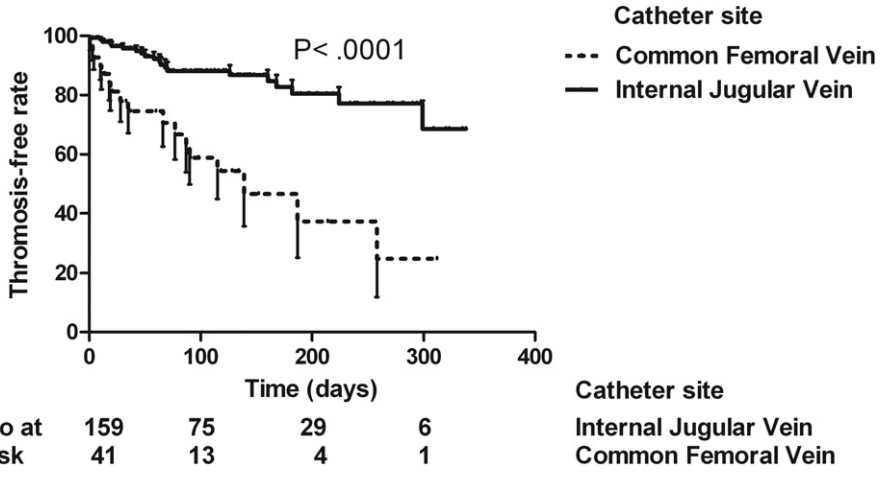


Figure 3. Graph shows the primary assisted patency of the TCCs in the common femoral and internal jugular veins. The primary assisted patency in the internal jugular vein was significantly greater than that in the common femoral vein ($P < .0001$). Error bars of the Kaplan-Meier survival curves represent the standard error; the number of patients at risk at each interval is also shown.

Patency Results

Primary assisted TCC patency was significantly reduced with the BioBloc TCC (71% and 61% at 90 and 180 days, respectively) compared with the Palindrome Ruby TCC (94% at 90 and 180 days) ($P < .0001$, **Fig 2**, **Table 2**). Primary assisted TCC patency was also significantly reduced in the common femoral vein (59% and 37% at 90 and 180 days, respectively) compared with the internal jugular vein (88% and 83% at 90 and 180 days, respectively; $P < .0001$, **Fig 3**). Primary assisted patencies of the BioBloc and Palindrome Ruby TCCs in the internal jugular and common femoral veins are shown in **Figure 4**. This was reduced for the BioBloc compared with the Palindrome Ruby TCCs in both locations, but the difference was significant only for the internal jugular vein location (**Fig 4a**, $P = .004$). The remaining clinical characteristics, including the presence of a fibrin sheath, had no influence on patency rates. Multivariate analysis identified only TCC type (BioBloc TCC) and common femoral access site as independent predictors of worse patency (**Table 3**). The unadjusted relative risk (95% confidence interval) for TTC dysfunction with the BioBloc TCC compared with the Palindrome Ruby TCC was 6.0 (2.33–15.53, $P < .001$), and the relative risk adjusted for access site was 3.2 (1.71–11.96, $P = .002$), as derived from the Cox regression model.

Infection Rates

The infection-free rates with the BioBloc TCC (84% and 68% at 90 and 180 days, respectively) and Palindrome Ruby TCC (81% and 62% at 90 and 180 days, respectively) were similar ($P = .36$, **Fig 5**, **Table 2**). The bacteriology results (from the blood and/or catheter tip) indicative of infection around the time of TCC removal are shown in **Table 4**. The frequency of methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE) increased from 10 of 37 cases (27%) around the time of insertion to 19 of 36 cases (53%) afterward ($P = .025$). Only nine of the 36 latter infections (25%) were repeat infections with the same microorganism.

The influence of infection around

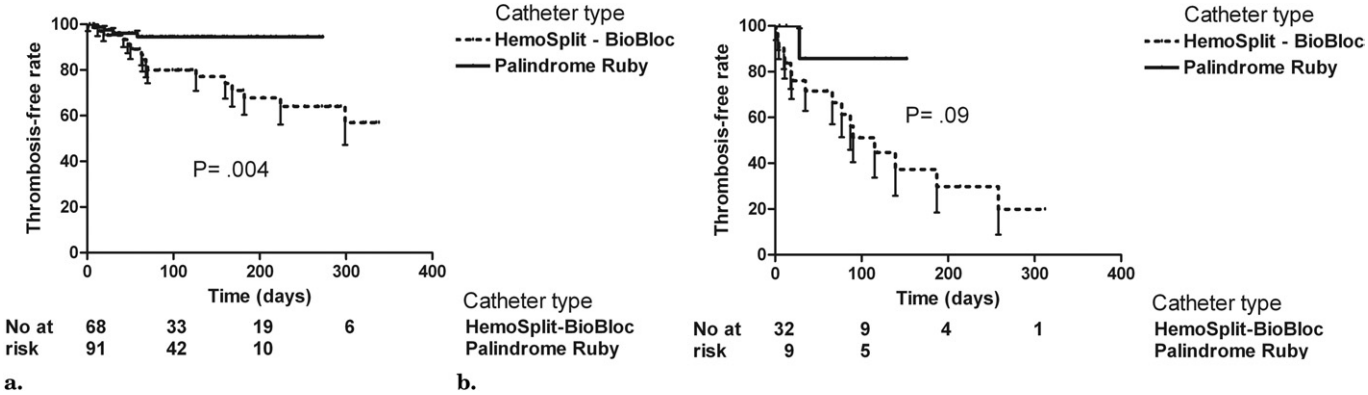


Figure 4. Graph shows the primary assisted patency of the BioBloc and Palindrome Ruby catheters in the internal jugular vein (**Fig 4a**) and common femoral vein (**Fig 4b**). The primary assisted patency with the Palindrome TCC was greater than that with the BioBloc TCC at both locations, but the difference was significant only for the internal jugular vein location (**Fig 4a**, $P = .004$). Error bars of the Kaplan-Meier survival curves represent the standard error; the number of patients at risk at each interval is also shown.

Table 3
Independent Predictors of TCC Thrombosis on Multivariate Analysis with the Cox Proportional Hazards Regression Method

Predictor	B	Standard Error	Wald Statistic	*P* Value	Exp(B) (Relative Risk)	95% CI for Exp(B)
BioBloc TCC	1.51	.50	9.27	.002	4.52	2.34–8.57
Common femoral vein access site	1.15	.34	11.39	.001	3.16	1.71–11.96

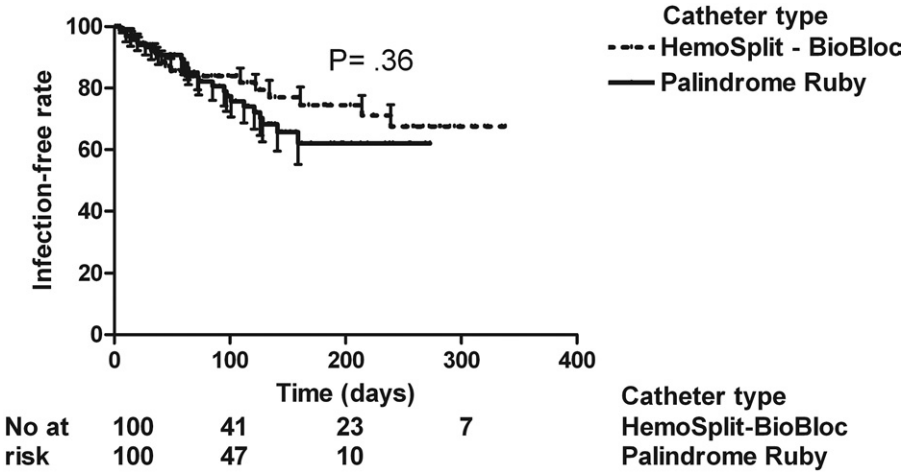


Figure 5. Graph shows the infection-free rates of the BioBloc and Palindrome Ruby TCCs. The difference was not statistically significant ($P = .36$). Error bars of the Kaplan-Meier survival curves represent the standard error; the number of patients at risk at each interval is also shown.

the time of TCC placement or exchange (bacteremia before catheter placement or exchange for infection) on infection rates is shown in **Figure 6**. The presence of infection around the time of TCC placement (more common with the Palindrome Ruby TCCs than with the BioBloc TCCs, **Table 1**) was associated with a significantly increased repeat infection rate ($P < .0001$) and was the only variable retained in a multivariate model (B = 1.22, standard error = 0.32, Wald = 14.9, $P < .001$, relative risk = 3.4, 95% confidence interval = 1.82–2.27). Compared to new placement of a catheter, exchange over a guide wire was not associated with an increased risk of infection in the absence of infection ($P = .24$) or when infection was present ($P = .96$).

TCC Site Loss Results

The reintervention-free rate for infection or malfunction was significantly better with the Palindrome Ruby TCC (76% and 58% at 90 and 180 days, respectively) than with the BioBloc TCC (60% and 45% at 90 and 180 days, respectively; $P = .03$; **Fig 7**, **Table 2**). Access site loss–free survival was similar in the two groups: 83% and 81% at 180 days for the BioBloc and Palindrome Ruby TCC, respectively ($P = .59$, log-rank test).

DISCUSSION

The results of our study show that the Palindrome Ruby catheter has a significantly reduced frequency of malfunction or thrombosis, requiring fewer catheter exchanges, compared with the HemoSplit BioBloc TCC. The most recent update of the KDOQI guidelines advised that although there

Table 4
Bacteriology Results Indicative of Infection around the Time of Placement or Removal of the TCC

Bacteria	Culture Results	
	Around the Time of TCC Insertion	Around the Time of TCC Removal
Staphylococcus		
S aureus	11*	15†
S hominis	1	
S epidermidis	2	5
Streptococcus pyogenes		1
Peptostreptococcus micros	1	
Enterococcus		
E faecalis	7	8‡
E faecium	1§	
Bacillus species	1	1
Citrobacter freundii		1
Enterobacter		
E aerogenes	1	
E cloacae	1	
Escherichia coli	3	
Klebsiella pneumoniae	3‖	3
Pseudomonas aeruginosa	1	1
Proteus mirabilis	2	
Providencia stuartii	1	
Serratia marcescens	2	
Xanthomonas maltophilia		1

Note.—Cultures were obtained from blood and/or the catheter tip.
* Nine patients had MRSA.
† Fourteen patients had MRSA. One patient had concomitant *E faecalis* and *E cloacae.*
‡ Five patients had VRE.
§ One patient had VRE.
‖ One patient had concomitant *Serratia marcescens*.

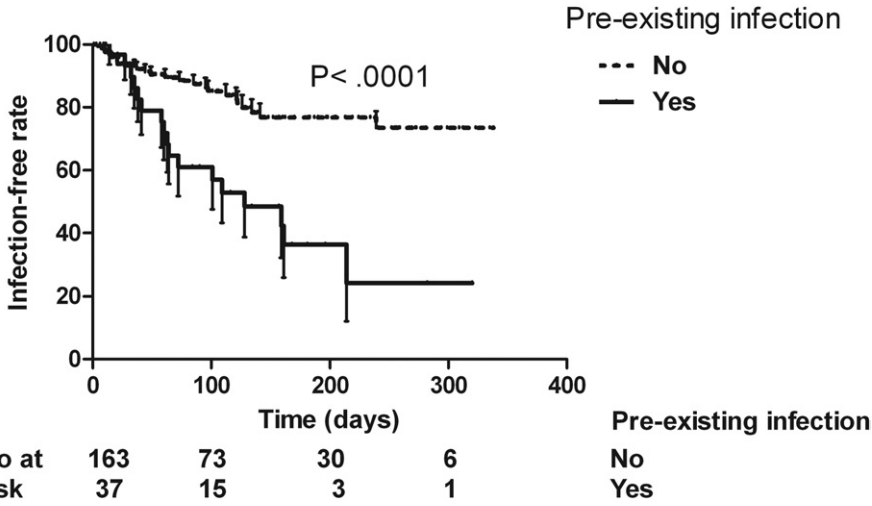


Figure 6. Graph shows the influence of pre-existing infection (bacteremia before catheter placement or exchange for infection) on infection-free rates of the TCCs. Pre-existing infection was associated with a significantly increased reinfection rate ($P < .0001$). Error bars of the Kaplan-Meier survival curves represent the standard error; the number of patients at risk at each interval is also shown.

is no proved advantage of one long-term catheter design over another, this area is undergoing intensive investigation (2). The results of our study should help update the KDOQI guidelines.

The target for TCC immediate failure rate has been set to no more than 5%, and the cumulative incidence of clinically significant insertion complications (eg, pneumothorax necessitating a chest tube, symptomatic air embolism, hemothorax, hemomediastinum, hematoma necessitating evacuation) should not exceed 2% of all catheter placements (KDOQI guideline 34) (1). Our results (1% primary failure rate and 0.5% significant insertion complications) compare favorably to the KDOQI recommendation, probably because we employ fluoroscopy for all cases and US for all new TCC placements. The single clinically significant insertion complication we encountered after the conversion of a temporary catheter (performed at an outside facility, probably without US guidance) to a TCC was most likely related to the previous puncture—a low and probably transpleural, innominate vein puncture—that resulted in temporary but substantial bleeding between temporary catheter removal and TCC placement. As described in Materials and Methods, we use US to guide the initial puncture with the 21-gauge needle and then use fluoroscopy to ensure that the 0.018-inch guide wire advances to the right atrium. In addition, after exchange, we advance the 0.036-inch guide wire to the inferior vena cava. Misplacement of the hemodialysis catheter to the brachiocephalic artery, necessitating surgery, has been described (14). Because of our very low complication rate and high technical success rate, the present study does not have enough power to detect any such difference between the two TCCs used in this study.

The KDOQI guidelines did not recommend a particular target rate for tunneled cuffed catheter thrombosis, although they acknowledged that it is a cause of high morbidity (1). TCC thrombosis-free rate at 180 days, necessitating catheter removal or exchange, has been reported to vary between 14% and 67% (average, 42%) (7,10,15–19). This is lower with femoral catheters (average, 35%) than with internal jugular vein catheters (aver-

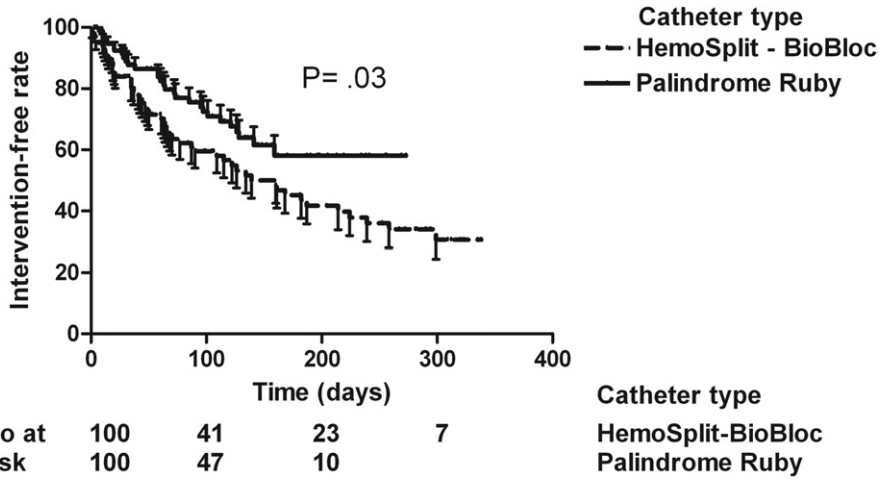


Figure 7. Graph shows the reintervention-free rate for infection or malfunction of the BioBloc and Palindrome Ruby TCCs. The reintervention-free rate was significantly reduced with the Palindrome Ruby TCC compared with the BioBloc TCC (P = .03). Error bars of the Kaplan-Meier survival curves represent the standard error; the number of patients at risk at each interval is also shown.

age, 48%). Although the thrombosis-free rate of the BioBloc TCC in the present study (61% at 180 days) is favorable compared to that in most of the published literature, it is significantly higher with the Palindrome Ruby TCC (94% at 180 days). Clinical experience with the BioBloc and Palindrome TCCs in two unrelated observational studies showed an incidence of thrombosis for each of these TCCs similar to that found in our study (5,20). Our study, although not randomized, was unique in the sense that we performed a direct comparison of the two TCCs. The reduced malfunction rate seen in the Palindrome Ruby TCC group, compared to the BioBloc group, should be attributed to the different tip design; the former also supports line reversal in case of poor catheter flow. Future studies could address the cause of catheter malfunction (eg, fibrin sheath, kink, or thrombus formation) in these two catheter types.

In our study, the two TCCs showed equivalent infection rates despite the fact that more Palindrome Ruby TCCs were placed for infection, which was the only parameter being associated with infection recurrence. The opinion of the KDOQI guideline authors for the recommended target rate of TCC systemic infection is that it should be less than 10% at 3 months and less than 50% at 1 year (guideline 32) (1). Our results in the subgroup of TCCs with no previous infection are well within the recommended targets. Infection rates in the literature vary from 0.25 to 6.5 per 1,000 catheter days, with most of them being in the 3–4 per 1,000 catheter days range (4,21–28). The total infection rate in our study—two per 1,000 catheter days—compares favorably with that in most series. The relative frequency of MRSA is not surprising and consistent with that of previous studies (29,30). Diabetes was not a risk factor for TCC infection in our study, possibly as a result of good control or the prevalence of other stronger risk factors. The TCC removal or exchange rate due to tunnel or exit site infection was low in our study, which is therefore not powered to look at the effect of different antimicrobial coating or sleeves in preventing this complication.

As a result of fewer reinterventions for thrombosis, the total reintervention rate was reduced with Palindrome Ruby TCCs compared with BioBloc TCCs. At the expense of more interventions to exchange thrombosed catheters in the BioBloc group, access site survival was similar in the two groups. Larger studies with longer follow-up are needed to determine the effect of TCC type on access site or access vein survival (12).

The main limitation of the current study is the nonrandomized design, which could have introduced bias because of different inclusion criteria, variable definition of endpoints, and/or use of different treatment modalities to manage the study endpoints. Although our practice patterns, including technical aspects, did not change within the relatively short time frame in which the study was conducted, a multicenter randomized controlled trial, stratified according to center, indication, and previous and final placement site to adjust randomization for confounding variables, would be desirable. Such a study could include a larger number of patients followed up for a longer period of time to address the key question of whether the addition of an antimicrobial coating prevents catheter, exit-site, or tunnel infection by including a control group without such coating. Currently, there is paucity of data to support the results of experimental studies on antimicrobial coating of hemodialysis TCCs (6) that are simply extrapolated to clinical practice. Further investigation of the effect of catheter tip design and material on the relative frequency of fibrin sheath or tip thrombus formation, which was not addressed in the current study, would be also worthwhile. Cost-effectiveness issues were not investigated in the current study; the use of more sophisticated catheters increases the overall cost of the procedure. Given the high failure rate of hemodialysis TCCs, even a small improvement in catheter performance will offset an increased catheter cost. This could be addressed in future studies.

In conclusion, the Palindrome Ruby TCC demonstrated a significantly reduced thrombosis and reintervention rate compared with the BioBloc TCC in this case-controlled study. Randomized trials are justified to confirm this finding and to evaluate its role in preventing TCC infection.

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