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Technical Note

Adequacy of haemodialysis with cuffed central-vein catheters

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Abstract. Cuffed central-venous haemodialysis catheters are emerging as an alternative permanent haemodialysis vascular access. There is limited data regarding the adequacy of dialysis with prolonged used of these catheters. We conducted a prospective study comparing three commonly used cuffed central-venous haemodialysis catheters: (1) PermCath™, Quinton Instrument Co, Seattle; (2) Tesio™, Med Comp, Inc, Harleysville PA; (3) VasCath Soft Cell™, Bard Instrument Company, Toronto, and compared them with control patients dialysing with arteriovenous access (AV) access. We randomly assigned 64 patients who needed prolonged temporary vascular access to placement of one of three catheters. The control group comprised 222 patients dialysing simultaneously in the same units with AV access.

Methods. All patients were dialysed with identical machines and kidneys. Maximal effort were made with every catheter to optimize achievable blood flow. Catheters with mechanical problems were treated first with urokinase and then fibrin sheath catheter stripping. The mean blood flow was determined by averaging mean blood flows from 30 consecutive treatments. Reliability of catheter was defined as percentage of treatments that were performed at a median blood flow of 350 ml/min or above during these 30 treatments. Kt/V was measured monthly and calculated using the single-pool Daugirdas formula. Haemodialysis prescription were adjusted for Kt/V above 1.2. Recirculation was measured using two-needle low-blood-flow technique.

Results. The mean blood flows were (PermCath 383.6 ml/min, Tesio 396.3 ml/min, VasCath 320.4 ml/min). PermCath and Tesio had comparable mean blood flows and were significantly higher than VasCath ($P<0.005$). Reliability of catheters were (PermCath 86.9%, Tesio 81.6%, VasCath 42.3%). Tesio and PermCath were equally reliable and both were more reliable than VasCath ($P<0.005$). Had the target for reliability been 300 ml/min all three catheters would have been equally reliable. Negative arterial pressure in excess of 300 mmHg prevented faster blood flows in 98% of instances. None of the catheters performed as well as the control population with AV access (mean blood flow 437 ml/min, reliability 96%, $P<0.005$). Recirculation rates were 3.7% for PermCath 3.9% for Tesio, and 4% for VasCath. All patients weighing less than 85 kg acheived a Kt/V of 1.2 with a 4-h treatment. For comparison purposes when Kt/V was normalized to a 70-kg patient the results were PermCath 1.42. Tesio 1.44, VasCath 1.19, AV access 1.64.

Summary. All three catheters are capable of providing adequate haemodialysis although large patients will need extended treatment times. The PermCath™ and Tesio™ provide blood flow and reliability superior to the VasCath™. Blood flow is limited in all catheters by inflow, as evidenced by negative arterial pressure. All catheters had acceptable recirculation. AV access is superior in terms of blood flow and reliability to all tested catheters.

Key words: adequacy; catheter; ESRD; haemodialysis; Kt/V; recirculation; renal failure; PermCath

Introduction

Haemodialysis requires reliable access to the circulation. This access to the circulation has traditionally been provided by native arteriovenous (AV) fistulae and synthetic AV grafts (AV access) [1–3]. Temporary access for haemodialysis has been provided by bedside inserted dual-lumen haemodialysis catheters [1–5]. Unfortunately, unsuitable vascular anatomy may preclude AV access formation in some patients. In other patients comorbid conditions and or haemodynamic instability may preclude AV access formation. In this group of patients, cuffed central-venous haemodialysis catheters are emerging as permanent vascular access [6–13].

Cuffed tunnelled central-venous haemodialysis catheters have longer use-life than dual-lumen acute haemodialysis catheters. These catheters inserted into the internal or external jugular veins were originally described in 1987–1988 as a means of prolonged temporary access [6–10]. Shortly thereafter several groups explored their role as permanent vascular access in selected subgroups of patients [7–13]. Subsequently these catheters have enjoyed a dramatic increase in use

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with multiple companies engaged in their manufacture. Several distinct catheter types designed for prolonged use are now on the market.

There are no available data regarding the adequacy of dialysis with the prolonged use of central-venous haemodialysis catheters. This is important since haemodialysis prescription may need to be adjusted according to catheter performance. A minimum Kt/V of 1.2 calculated with a single-pool model is now recommended for chronic haemodialysis patients in the US. We conducted a prospective study comparing commonly used central-venous cuffed haemodialysis catheters to patients with permanent access *via* AV fistula or AV graft to determine the reliability of the catheters to deliver adequate haemodialysis in a diverse group of patients.

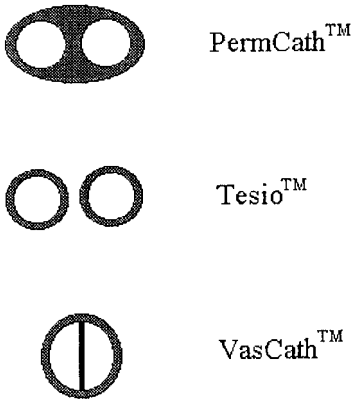

Fig. 1. Schematic description of the lumina of the three tested catheters.

Subjects and methods

Study design

Between 1993 and 1995 we randomly assigned 64 consecutive Duke University haemodialysis patients who required prolonged temporary vascular access to placement of one of three distinctly different types of commonly used central-venous cuffed haemodialysis catheters. Comparisons were made between the three catheter types and a control population of patients who had vascular access with either primary AV fistulae or polytetrafluoroetheylene (PTFE) AV grafts (AV access).

To compare access function between different catheter designs and AV access we defined three different parameters by which we could measure access function. They were: (1) mean blood flow achieved during 30 consecutive dialysis treatments, (2) access reliability defined as the percentage of dialysis treatments during which a blood flow of 350 ml/min could be achieved for the majority of the treatment during these 30 treatments, and (3) delivered dose of dialysis as measured by Kt/V

Catheters tested

1. PermCath™ (Quinton Instrument Co. Seattle),
2. Tesio™ (Med Comp, Inc. Harleysville PA) and
3. VasCath Soft Cell™ (Bard Instrument Company, Toronto).

A total of 286 patients were enrolled in the study between October 1993 and December 1995. All hospital and radiology procedures were done at the Duke University Medical Center and patients were dialysed at one of three haemodialysis units affiliated with Duke University. Data was collected in regard to mean and median blood flow and duration of haemodialysis at each haemodialysis session and was entered into a database. Urea kinetic modelling was performed monthly using a-single pool Daugardis formula [14].

Catheters/AV access

The catheters used in this study represent three distinctly different designs of catheter with different internal cross-sectional areas. In the double-lumen catheters arterial and venous end-holes are separated by several centimetres to minimize recirculation. The distal end is used as a return port and the proximal end as an inflow port.

PermCath is an oval catheter with two separate round lumina and has the largest external diameter of the tested catheters. The Tesio catheter has two separate single lumina that require two catheter insertions. The VasCath Soft Cell has a single circular lumen with a midline septum. Physical characteristics of each catheter are shown in Figure 1.

PermCaths were placed by vascular surgery in the operating rooms of the Duke University Medical center as has been previously described [6,15]. The catheter was inserted into the central vein with a modified Seldinger technique using a unique oval peel-away sheath designed for the catheter. The catheter was finally positioned fluoroscopically for its tip to lie at the atrial–caval junction or just inside the right atrium. Our experience is that the size and shape of this catheter make it the most difficult of the three tested catheters to insert percutaneously. Insertion locations were 63.6% in the right internal jugular vein (RIJ), 4.4% in the left internal jugular vein (LIJ), 26% in the external jugular vein (EJ), and 6% in the subclavian vein (S)

Tesio catheters were placed in the central vein *via* percutaneous cannulation with modified Seldinger technique in the interventional radiology suites under fluoroscopic guidance. The outflow catheter was introduced in the vein 4 cm deeper than the inflow catheter. The tip of the venous 'return' catheter was positioned at the atrial–caval junction or just inside the right atrium (83.3% RIJ, 12.5% LIJ, 4.2% EJ).

VasCaths were placed using a technique similar to the PermCath. Radiologists felt this was the easiest catheter to insert due to round shape, sturdy construction, and small external diameter. The central vein was approached using modified Seldinger technique. The catheter was then tunnelled through subcutaneous tissue and final position of the tip of catheter was the same as the PermCath. A round peel-away sheath is used for this insertion. These catheters were inserted in the vascular radiology suites under fluoroscopic guidance (55% RIJ, 5% LIJ, 25% EJ, 15% S).

AV access comprised 29% AV fistula (62% radial cephalic, 38% brachial cephalic) and 71% AV grafts in multiple configurations and placement locations (100% PTFE).

Haemodialysis

All patients were dialysed with Cobe Centry 3 volumetric haemodialysis machines at maximum blood flow that the catheter allowed. Blood flow was read from the blood pump

Table 1. Catheter types and characteristics

Catheter	Type	Internal diameter	Distance between proximal and distal ends
PermCath™	Dual-lumen	2 mm	2.5 cm
Tesio™ catheter	Two single lumina	2 mm	4 cm
VasCath™	Single circular lumen with midline septum	2.5 mm	2.5 cm

of the haemodialysis machine. Dialysate flow rates were 600 ml/min (maximum for Cobe Centry 3). Blood flow rates were inhibited by either exceeding maximum machine tolerated venous pressure of 350 mmHg or by falling below an the machine tolerated maximum negative arterial pressure of −300 mmHg. Blood flow rates were recorded every 30 min. Median blood flow of each dialysis treatment was used to represent the achievable blood flow at each individual treatment (catheter reliability). Mean blood flow was calculated at each treatment. The mean of 30 consecutive treatment blood flows is reported as mean catheter blood flow. Aggressive attempts to maximize catheter function were employed as previously reported from our centre [15]. Techniques for the maintenance of adequate blood flow in catheters were as previously described by us, including use of urokinase and fibrin stripping by vascular radiology [6,15,16]. Eighty nine per cent of patients were dialysed using F-80 dialysers (Fresenius USA, polysulphone, 1.8 m^2, KUf 30.55). Haemodialysis prescriptions were adjusted for Kt/V to exceed a minimum of 1.2. Data on control patients with AV access was obtained in a manner identical to catheter study patients.

Urea kinetic modelling for catheter patients was measured monthly and calculated from single-pool Daugirdas formula with the post sample obtained 30 s after the cessation of haemodialysis [14]. For the comparison of Kt/V only patients dialysed with the F-80 kidney were included in the analysis (89% of total catheter patients, 92% of control AV access patients). The recirculation rate was measured with low blood flow technique [17]. Recirculation rates were measured at the start of the haemodialysis treatment.

Demographic data

Sixty-four consecutive patients were enrolled in the study, 57 were African-American, 31 were male. Mean age of the catheter study population was 53 ± 7 years. Thirty-three patients had ESRD from DM. Detailed demographic data for each group is shown in Table 2.

Statistical methods

Differences between continuous variables were compared using the paired *t* test and differences between categorical variables were analysed using the chi-squared test. Because of differences in body weights among patients with various forms of access, Kt/V was adjusted for each group in order to facilitate comparisons (adjusted Kt/V Table 3).

These adjustments were performed to normalize each group to a body-weight of 70 kg by using linear regression analysis All analyses were performed using the SAS statistical software package (Carey, NC).

Table 2. Demographic data of patients

	Control	PermCath	Tesio	VasCath
Patients (*n*)	222	22	24	18
African-American : caucasian	171 : 51	19 : 3	21 : 3	17 : 1
Male : female	121 : 101	12 : 10	12 : 12	7 : 11
ESRD from DM	117/222	9/22	15/24	9/18

Results

Mean blood flow

Mean blood flow for patients with AV fistulae and PTFE grafts was 437 ± 18 ml/min (Table 3). The mean blood blood flow for PermCaths was 384 ± 28 ml/min, for Tesio catheters was 396 ± 45 ml/min, and for VasCath catheters was 320 ± 62 ml/min. The mean blood flows were not different between PermCath and Tesio catheters; however, the VasCath had a significantly lower blood flow compared to either of these catheters ($P < 0.005$). All three catheters had significantly lower blood flows compared to control patients with AV access ($P < 0.005$). Arterial negative pressure limited flow in 95% of cases. (Table 3).

Reliability of access

Ninety-six per cent of dialysis treatments delivered with AV access achieved blood flows of 350 ml/min (access reliability). In contrast, 87% of haemodialysis treatments using PermCath were performed at blood flows of 350 ml/min, with 82% for Tesio catheters and 46% for VasCath. The reliability of the PermCath and Tesio catheters was significantly better than that of the VasCath ($P = 0.005$), and the reliability of all three catheters was significantly inferior to AV access ($P = 0.005$) (Table 3).

Urea kinetic modelling Kt/V and treatment time

All haemodialysis treatments were performed at maximal blood flow that each type of catheter could provide and in general patients with AV access were dialysed at blood flows of between 400 and 500 ml/min. All patients in the PermCath and control group achieved a Kt/V of 1.2 in 4 h of therapy. Three patients with Tesio catheters and three patients with VasCaths had Kt/V < 1.2 and all had dry weights above 85 kg and were not willing to extend treatment time beyond 4 h. The mean treatment times were not significantly different between the three groups. The mean dry

Table 3. Adjusted Kt/V

	AV Access	PermCath	Tesio	VasCath
Mean blood flow[2,3]	437 ± 18	384 ± 28.5	396 ± 45.1	320 ± 62
Reliability %[3]	96	87	82	46
Mean Kt/V	1.44 ± 0.17	1.42 ± 0.16	1.39 ± 023	1.321 ± 0.2
Adjusted Kt/V[2,3]	1.64	1.42	1.44	1.19
Mean dry weight (kg)	81.3	68.4	77.4	61.1
Recirculation % rate	4.4	3.7	3.9	4

[1]Difference between AV Access and PermCath or Tesio catheter <0.005.
[2]Differcnce VasCath and PermCath or Tesio catheter <0.005.
[3]Difference between AV access and all types of catheter.

weights for patients with AV access was 81.3 kg, for patients with PermCaths it was 68.4 kg, for the Tesio catheter group it was 77.4 kg, and the weight for the VasCath group was 61.1 kg (Table 3).

The consecutive selection of patients resulted in significant differences in dry weights between groups. In order to facilitate comparison of delivered dose of dialysis between catheter types we adjusted the analysis to look at the adjusted Kt/V for a 70-kg person. The mean adjusted Kt/V for patients with a VasCath was significantly lower than in patients with either AV access, PermCath, or Tesio access, and all catheters were significantly lower than the control group with AV access.

Recirculation

Recirculation was compared between the three catheter types using low blood flow techniques [17]. The average mean recirculation rate is 3.7% for PermCath, 3.9% for the Tesio catheter, and 4% for VasCath at a blood flow of 400 ml/min in those catheters that would reach 400 ml/min. Mean recirculation for the control population was 4.4%.

Discussion

Adequate haemodialysis requires adequate extracorporeal blood flow. Current high-efficiency haemodialysers with surface area $>1.6\ m^2$ require blood flow of at least 350 and preferably 400 ml/min to reach maximum efficiency. The minimum acceptable haemodialysis dose in the US is now a urea reduction of 65% or a Kt/V of 1.2 using single-pool urea kinetics [18]. Thus, failure to reliably provide extracorporeal blood flows of 350–400 ml/min limits the efficiency of the dialyser and requires longer treatment times. At our centre many patients are unwilling to increase dialysis times beyond 4 h three times per week. In addition, access malfunction that results in non-optimal blood flow on multiple days also impairs haemodialysis delivery. Therefore, maximum blood flow as well as reliability of the access are essential to delivering an adequate dose of haemodialysis.

It has been shown that blood flows read from dialysis machine blood pumps overestimate the true blood flow when approaching higher negative pump pressures [19]. Theoretical considerations would predict that the circular lumen with midline septum has 20–30% higher resistance to flow than circular lumina [20]. Our study confirms that catheters with distinct circular lumina (PermCath and Tesio catheters in this study) are able to provide blood flow rates significantly higher than a catheter with a midline septum (VasCath, $P<0.005$). None of the tested catheters approached the blood flow rate provided by AV access. In addition the AV accesses reached their machine-read blood flow at much more favourable negative prepump pressures, suggesting that machine-read blood pump speed was much more accurate with AV access.

Central-venous haemodialysis catheters are vulnerable to catheter-related thrombosis, fibrin sheath formation, and other mechanical problems which will adversely affect maximal achievable blood flow rate and reliability [15,16]. We and others have reported techniques for resolving catheter malfunction, including intracatheter urokinase and percutaneous stripping of the fibrin sheath, and exchanging the catheter over a guidewire [15,16]. Patients enrolled in this study underwent aggressive treatment of catheter malfunction with urokinase as first-line therapy and catheter stripping of fibrin sheaths as treatment for refractory malfunction [6,15,16]. Despite these efforts, reliability of all tested catheters was not as good as AV access.

Reliability of catheters in this study was determined by the percentage of haemodialysis treatment performed with blood flow >350 ml/min. AV access provided the most reliable means of vascular access, with 96% of dialysis treatments achieving the target blood flows compared to 87 and 82% for the PermCath and Tesio catheters respectively. Both PermCath and Tesio catheters were more reliable than VasCath ($P<0.005$) in the achievement of this goal. However, none of the catheters achieved the reliability of the control population with AV access. Had the goal for reliability been 300 ml/min all three catheters would have been equally reliable.

The mean (Kt/V) was 1.42 for patients with PermCath, 1.39 for the Tesio catheter, and 1.32 for VasCath. When these Kt/V are adjusted to a 70-kg patient to eliminate effects caused by patient weight differences, the results are AV access 1.64, PermCath

1.42, Tesio 1.44, and VasCath 1.19. Thus it is clear that all the catheters would require extended treatment time to deliver the equivalent dose of dialysis compared to AV access. In addition, Kt/V measures only an ideal dialysis session or provides a snapshot of potential dialysis dose. Reliability of the access is crucially important in delivering a total dialysis dose. In this assessment none of the catheters approached the reliability of the control group with AV access. Interestingly, if the target extracorporeal blood flow were 300 ml/min all three catheters would have been equally reliable. Thus, if longer treatment times and slower blood flows were the rule, as in some European centres, all three catheters would have performed equally.

Each catheter had an average recirculation rate of 4% at blood flows of 350–400 ml/min. Thus, if the catheters lumina are not reversed, urea recirculation does not seem to substantially increase with increasing blood flows. Rather it is negative arterial prepump pressure that limits achievable blood flows and limits dialysis efficiency.

In summary, currently available cuffed haemodialysis catheters when placed at the atrial caval junction provide adequate access for haemodialysis. Catheters with two distinct lumina rather than a midline septum appear to provide both better sustained higher blood flows and more reliable blood flows. None of the tested catheters provided blood flow or access reliability to match the flows and access reliability provided by patients with AV access. To reach an equivalent dose of haemodialysis, patients dialysing with cuffed central-vein tunnelled catheters will in general require longer treatment times than those dialysing with AV access.

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