Shaldon Katheter im „Raulerson Design“ für extra lange Liegezeiten

Seite	Shaldon Katheter mit „Raulerson Design“
1	**Was bedeutet „Raulerson Design“**
2	**Indikationen**
3	**Gegenüberstellung „Raulerson Design“ vs. Gerade Lumina**
4	**Punktion eines Shaldon Katheters mit „Raulerson Design“**
5	**Fixierung**
6	**Flussraten**

„Raulerson Design“ meint ein um 180° vorgebogenes Katheterlumen

Shaldon Katheter im Raulerson Design

- Der Begriff „Raulerson Design“ bezeichnet Shaldonkatheter mit einem bereits um 180° vorgebogenem Lumen
- Der amerikanische Nephrologie J. DANIEL RAULERSON hat dieses Katheterdesign erstmalig konzipiert, um – zusammen mit einer abweichenden Punktion – eine deutlich längere Liegezeit von Shaldonkathetern als 2 Wochen +/- zu erwirken

Shaldon Katheter mit geradem Lumen

- Doppel- und dreilumige Shaldonkatheter mit geraden Lumina sind in Deutschland aufgrund der bisher geringen Bekanntheit des „Raulerson Designs“ der Standard Shaldonkatheter in den meisten Kliniken in Deutschland

Indikationen

Shaldon Katheter im Raulerson Design

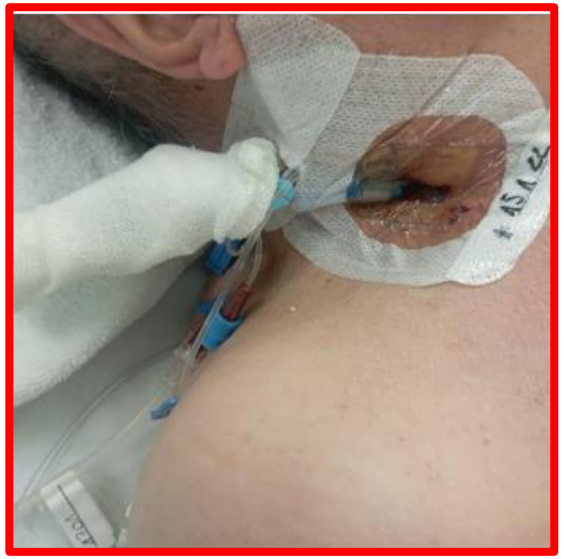
- **Indikationen (Hämodialyse bis hin zu mehreren Monaten)**
  - **Akutdialyse**
  - **Shuntüberbrückung / Shuntrevision**
  - **Temporäre HD bei PD Katheterinfektionen**

Das „Raulerson Design“ ermöglicht extra lange Liegezeiten bei Shaldonkathetern

Shaldon Katheter im Raulerson Design

- \+ Liegezeit von 3 Monaten + durch verringerte Exitinfektionen
- \+ Höherer Patientenkomfort
- \+ Einfacherer Zugang zum Verbinden
- \+ Einfacherer Zugang zum An- und Abschließen der Blutschläuche

Shaldon Katheter mit geradem Lumen*

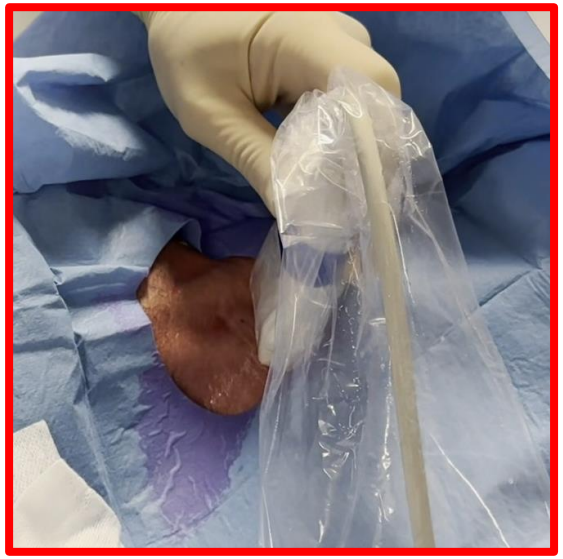


- \- Liegezeit lediglich bis zu 2 Wochen (im Regelfall)
- \- Ständige Reibung im Hals- Ohrenbereich der Patienten
- \- Erhöhte Reizung des Exits durch das An- und Abschließen der Blutschläuche

* Quelle | Universitätsspital Basel (https://www.unispital-basel.ch/dam/jcr:d16bee53-3203-474b-a6ce-6b01347fbf14/pflegerichtlinien_7_5_1.pdf)

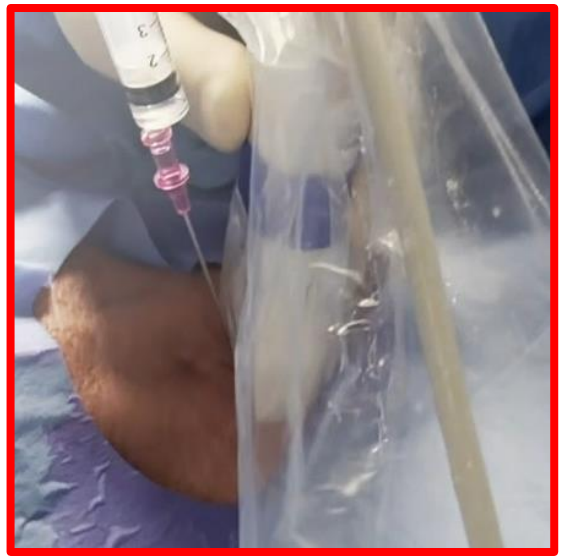
Bei der Implantation sind 3 wesentliche Punkte zu beachten

1 Sonographische Unterstützung



- Die Punktion muss mit sonographischer Unterstützung erfolgen, um eine Fehlpunktion zu vermeiden
- Der Ultraschallkopf wird direkt oberhalb der Clavicula positioniert

2 Punktion



- Die Punktionsnadel wird in einem steilen Winkel - ca. 80° - gehalten
- Nur so ist sichergestellt, dass bei der Punktion die Spitze der Punktionsnadel im Ultraschall zu sehen ist

3 Einführungen des Katheters

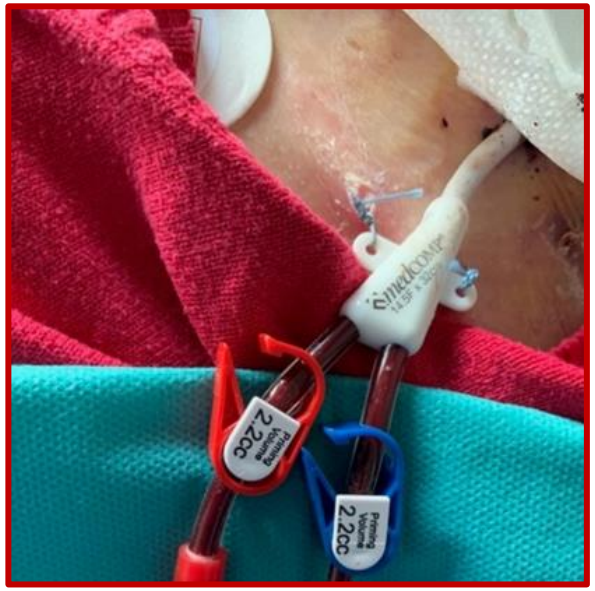
- Der Katheter muss so weit in die Vena Jugularis Interna vorgeschoben werden, sodass nur noch ca. 1-2cm des Lumens extracorporal sichtbar sind mit einer caudal ausgerichteten Exitstelle

Katheterfixierung

Fixierung mit CathFix

- \+ CathFix ermöglicht die Fixierung von Hämdodialysekathetern, PICC‘s und ZVK‘s
- \+ Die Anbringung ist einfach, schnell und sicher
- \+ Geeignet für Shaldonkatheter und Vorhofkatheter bis die Dracon Muffer mit der Haut verwachsen ist

Fixierung mit Annähöse



- \- Bei der Fixierung des Katheters mit der Annähöse kann es zu Reizungen und Infektionen der Nahtstellen kommen

Flussraten

	Herstellerangaben		Klinikdialysen*	
	V in ml/ min	A in ml/ min	V in ml/ min	A in ml/ min
12FR / 15cm	***~ 260***	***~260***	***~200-220***	***~200-220***
12FR / 20cm	**~240**	**~240**	**~180-200**	**~180-200**
14FR / 15cm	***~340***	***~340***	***~260-310***	***~260-310***
14FR / 20cm	**~330**	**~330**	**~220-260**	**~220-260**

Einflussfaktoren auf Flussraten

- Die Einflussfaktoren auf die zu erzielenden Flüsse sind vielseitig
- Herstellerangaben beruhen auf Optimalbedingungen im Labor

Grundsätzlich gilt |

- Jeder Patient ist anders
- Ist der Katheter richtig implantiert, bzw. die ist die Spitze richtig positioniert
- Katheterpflege / Blocken
- Bei Exsikkose erzielen alle Katheter schlechtere Flüsse
- Erst ab gewissen Stückzahlen kann verlässlich gesagt werden, ob ein System funktioniert oder nicht

* Quelle | Durchschnittliche Angaben von 27 Klinikdialysen. Jede Dialyse setzt mindestens 40 Stück des vorgebogenen Shaldonkatheters p.a. ein.

med Komp GmbH | Sitz: Haltern am See Amtsgericht Gelsenkirchen HRB 14701

UST-ID-Nr. DE319 179 276 | Steuer Nr. 359 5903 4177

Geschäftsführer: Dr. Bernd Henneberg

MFFS Raulerson Free Flow Katheter

Der Freeflow - Shaldonkatheter von medcomp hat im Ggs. zu den geraden Akutdialysekathetern ein um 180 Grad gebogenes Lumen, das als Raulerson – Design (der Katheter wurde von medcomp zusammen mit dem amerikanischen Nephrologen Dr. Daniel Raulerson entwickelt.) bezeichnet wird.

Er hat dadurch eine caudale Ausrichtung mit einer tieferen Punktionsstelle direkt über dem Claviculum in der vena iugularis interna. Er wird an der Brustwand fixiert, nicht am Hals.

Der Katheter erreicht Liegezeiten von 3 Monaten und länger. Der Patient kann mit diesem Katheter nach Hause geschickt werden und muss nicht -wie gewöhnlich bei Kathetern mit geraden Lumina- in der Klinik verbleiben.

Der Raulerson Katheter eignet sich zur Shuntüberbrückung und ersetzt damit einen untertunnelten Langzeitdialysekatheter.

Infektionsbedingte Katheterwechsel und Bakterämien sind stark reduziert, die Offenheitsrate (patency) ist deutlich erhöht, was zu einer wesentlich längeren Einsatzdauer (survival rate) als bei geraden Shaldonkathetern führt.

Die Gründe hierfür sind:

1. Coaxialdesign der Lumina

Die beiden Lumina liegen ineinander mit einer gemeinsamen Achse, was als Coaxialdesign bezeichnet wird. Es gibt keine Seitenlöcher und damit auch kein Festsaugen an den Gefässwänden, Locklösungen werden nicht ausgespült. Aufgrund dieser Konstruktion hat der Raulerson Katheter gute Flusseigenschaften.

2. Die Lage

Der gesamte Katheter ist caudal ausgerichtet, sodass er im Ggs. zu den geraden cranial ausgerichteten Shaldonkathetern zu jeder Zeit ruhig liegt: Er wird an der Brustwand fixiert und durch Kopf-, Hals-, Nackenbewegungen des Patienten nicht bewegt. Dadurch bleibt die Exitstelle vor Läsionen, die zu Infektionen führen können, geschützt. Durch diese Lage weist der Raulerson-Katheter ein sehr geringes Infektionsrisiko an der Exitstelle auf: häufige

Katheterwechsel, die bei Kathetern mit geraden Lumina regelhaft ist, gibt es beim Raulerson Katheter nicht.

3. Die Fixierung

Sie erfolgt an der Brustwand und nicht am Hals. Der Raulerson-Katheter hat dadurch eine wesentlich grössere Lagestabilität als ein gerader Shaldonkatheter. Ständige Hals- / Kopfbewegungen beeinflussen ihn nicht.

4. Das Handling

Bei geraden Shaldon - Kathetern findet 3 x wöchentlich durch Verbandswechsel und An- sowie Ablegen des Blutschlauchsystems eine starke Bewegung des Katheters u. damit eine Reizung der Exitstelle statt. Der Raulerson - Katheter wird durch diese Tätigkeiten nicht bewegt. Der Anschluss an das Blutschlauchsystem ist einfacher.

5. Drainage

Der Drainage von Sekreten an der Exitstelle erfolgt bei caudaler Ausrichtung besser als bei der cranialen von geraden Kathetern: bei diesen sammeln sich eher Sekrete u. Ablagerungen an der Exitstelle und führen zu Infektionen.

6. Katheterverband

Der Verband ist beim Raulerson-Katheter wesentlich einfacher vom Pflegepersonal anzubringen als bei geraden Kathetern. Die Exitstelle wird geschont.

7. Patientenkomfort

Der Raulerson-Dialysekatheter ist durch diese Merkmale für Patienten wesentlich komfortabler als ein Shaldonkatheter mit geraden Lumina. Der Patient bemerkt den Katheter nicht. Die Bewegungen des Kopfes werden nicht beeinträchtigt.

Die Langzeitstudie Studie von MC Weijmar u.a (NDT 2008 23; 977 - 983) belegt die überzeugenden Leistungsmerkmale des Raulerson Katheters während eines vierjährigen Beobachtungszeitraums, in welchem die Ergebnisse zusammengetragen und ausgewertet wurden.

FREE FLOW® ORDERING INFORMATION

Short-Term Free Flow

12.5FR Straight	***Sets (5/Box)***
12.5FR X 15cm Straight Short-Term Free Flow with Stylet Catheter Set	MFFS1215S
12.5FR X 20cm Straight Short-Term Free Flow with Stylet Catheter Set	MFFS1220S
12.5FR X 24cm Straight Short-Term Free Flow with Stylet Catheter Set	MFFS1224S

15.5FR Straight	***Sets (5/Box)***
15.5FR X 15cm Straight Short-Term Free Flow with Stylet Catheter Set	MFFS1515S
15.5FR X 20cm Straight Short-Term Free Flow with Stylet Catheter Set	MFFS1520S
15.5FR X 24cm Straight Short-Term Free Flow with Stylet Catheter Set	MFFS1524S

12.5FR Raulerson IJ	***Sets (5/Box)***
12.5FR X 12cm IJ Short-Term Free Flow with Stylet Catheter Set	MFFS1212IJ
12.5FR X 15cm IJ Short-Term Free Flow with Stylet Catheter Set	MFFS1215IJ
12.5FR X 20cm IJ Short-Term Free Flow with Stylet Catheter Set	MFFS1220IJ

15.5FR Raulerson IJ	***Sets (5/Box)***
15.5FR X 12cm IJ Short-Term Free Flow with Stylet Catheter Set	MFFS1512IJ
15.5FR X 15cm IJ Short-Term Free Flow with Stylet Catheter Set	MFFS1515IJ
15.5FR X 20cm IJ Short-Term Free Flow with Stylet Catheter Set	MFFS1520IJ

12.5FR IJ with 2 Wings	***Sets (5/Box)***
12.5FR x 12cm IJ Short-Term Free Flow with Stylet and 2 Suture Wings	MFFS1212IJ-2
12.5FR x 15cm IJ Short-Term Free Flow with Stylet and 2 Suture Wings	MFFS1215IJ-2
12.5FR x 20cm IJ Short-Term Free Flow with Stylet and 2 Suture Wings	MFFS1220IJ-2

15.5FR IJ with 2 Wings	***Sets (5/Box)***
15.5FR x 12cm IJ Short-Term Free Flow with Stylet and 2 Suture Wings	MFFS1512IJ-2
15.5FR x 15cm IJ Short-Term Free Flow with Stylet and 2 Suture Wings	MFFS1515IJ-2
15.5FR x 20cm IJ Short-Term Free Flow with Stylet and 2 Suture Wings	MFFS1520IJ-2

Set contains: (1) Catheter with Stylet, (3) Vessel Dilators, (1) J-Flex Guidewire, (1) Introducer Needle, (2)End Caps

medCOMP®

No Sideholes / Open Tips

FREE FLOW®

Medical Components, Inc.
1499 Delp Drive, Harleysville, PA 19438 USA
Tel: 215-256-4201 | Fax: 215-256-1787
medcompnet.com

CE 2797

PN 2476 Rev. F 3/19

medcompnet.com

FREE-FLOW®

Short Term Hemodialysis Catheter

Rotating Suture Wing
Rotating suture wing provides greater patient comfort.

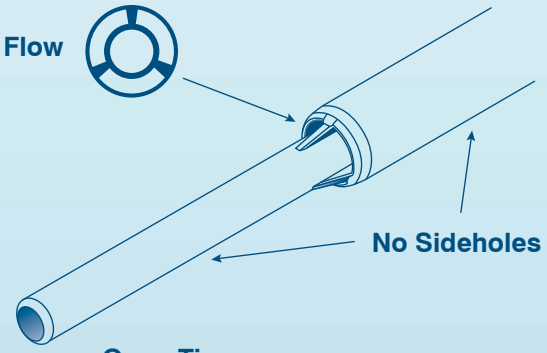
Raulerson IJ

Soft Tip Stylet (Short Term)
Helps with a less traumatic and fast insertion.

MRI Safe

Pre-Loaded Stylet
Allows for standard or modified seldinger introduction.

True 360° Flow



Open Tips
Open tip designed for unobstructed uptake and return to maximize flow

medcompnet.com

FREE FLOW®

FREE FLOW

Die neue Generation des Shaldonkatheters

1

- Der Ultraschallkopf wird direkt oberhalb des Claviculums gehalten und in dessen Richtung geneigt

2

- Die Punktionsnadel wird in einem steilen Winkel (ca. 80°) gehalten, um die Vene sicher zu punktieren und die Gefahr eines Pneumothorax auszuschließen

3

- Durch Kompression ist die zu punktierende Vene deutlich zu erkennen

4

- Das Gefäß wird punktiert

5

- Der MFFS Free Flow Katheter wird über den Führungsdraht in das Gefäß vorgeschoben

6

- Nach Einführung in das Gefäß , wird der Führungsdraht samt Mandrin in einem Zug aus dem venösen Schenkel herausgezogen

7

- Der MFFS Free Flow Katheter ist erst dann richtig gelegt, wenn nur noch ca. 1-2 cm des Lumens extrakorporal sichtbar sind

8

- Der MFFS Free Flow Katheter legt sich sodann aufgrund des vorgebogenen Lumens über das Claviculum, wird von diesem gehalten und liegt vollständig ruhig.

Es gibt bereits deutsche Referenzkliniken, bei denen der Free Flow Katheter seit vielen Jahren eingesetzt wird. Bei Interesse kann auch ein direkter Kontakt mit Dr. Marcel Weijmer vereinbart werden.

medKomp

MFFS FREE FLOW

Der Freeflow - Shaldonkatheter von medcomp hat im Ggs. zu den geraden Akutdialysekathetern ein um 180 Grad gebogenes Lumen, das als Raulerson – Design (der Katheter wurde von medcomp zusammen mit dem amerikanischen Nephrologen Dr. Daniel Raulerson entwickelt.) bezeichnet wird.

Der jetzige MFFS Free Flow Katheter mit dem neuen Coaxial Design wurde von medcomp zusammen mit dem niederländischen Nephrologen Dr. Marcel Weijmer entwickelt. Er hat dadurch eine caudale Ausrichtung mit einer tieferen Punktionsstelle direkt über dem Claviculum in der vena iugularis interna. Er wird an der Brustwand fixiert, nicht am Hals. Der Katheter erreicht Liegezeiten von 3 Monaten und länger. Der Patient kann mit diesem Katheter nach Hause geschickt werden und muss nicht -wie gewöhnlich bei Kathetern mit geraden Lumina- in der Klinik verbleiben. Der Raulerson Katheter eignet sich zur Shuntüberbrückung und ersetzt damit einen untertunnelten Langzeitdialysekatheter.

Infektionsbedingte Katheterwechsel und Bakterämien sind stark reduziert, die Offenheitsrate (patency) ist deutlich erhöht, was zu einer wesentlich längeren Einsatzdauer (survival rate) als bei geraden Shaldonkathetern führt.

1 Coaxialdesign der Lumina

Die beiden Lumina liegen ineinander mit einer gemeinsamen Achse, was als Coaxialdesign bezeichnet wird. Es gibt keine Seitenlöcher und damit auch kein Festsaugen an den Gefässwänden, Locklösungen werden nicht ausgespült. Aufgrund dieser Konstruktion hat der Raulerson Katheter gute Flusseigenschaften.

2 Die Lage

Der gesamte Katheter ist caudal ausgerichtet, sodass er im Ggs. zu den geraden cranial ausgerichteten Shaldonkathetern zu jeder Zeit ruhig liegt: Er wird an der Brustwand fixiert und durch Kopf-, Hals-, Nackenbewegungen des Patienten nicht bewegt. Dadurch bleibt die Exitstelle vor Läsionen, die zu Infektionen führen können, geschützt. Durch diese Lage weist der Raulerson-Katheter ein sehr geringes Infektionsrisiko an der Exitstelle auf: häufige Katheterwechsel, die bei Kathetern mit geraden Lumina regelhaft ist, gibt es beim Raulerson Katheter nicht.

3 Die Fixierung

Sie erfolgt an der Brustwand und nicht am Hals. Der Raulerson-Katheter hat dadurch eine wesentlich grössere Lagestabilität als ein gerader Shaldonkatheter. Ständige Hals- / Kopfbewegungen beeinflussen ihn nicht.

4 Das Handling

Bei geraden Shaldon - Kathetern findet 3 x wöchentlich durch Verbandswechsel und An- sowie Ablegen des Blutschlauchsystems eine starke Bewegung des Katheters u. damit eine Reizung der Exitstelle statt. Der Raulerson - Katheter wird durch diese Tätigkeiten nicht bewegt. Der Anschluss an das Blutschlauchsystem ist einfacher.

5 Drainage

Der Drainage von Sekreten an der Exitstelle erfolgt bei caudaler Ausrichtung besser als bei der cranialen von geraden Kathetern: bei diesen sammeln sich eher Sekrete u. Ablagerungen an der Exitstelle und führen zu Infektionen.

6 Katheterverband

Der Verband ist beim Raulerson-Katheter wesentlich einfacher vom Pflegepersonal anzubringen als bei geraden Kathetern. Die Exitstelle wird geschont.

7 Patientenkomfort

Der Raulerson-Dialysekatheter ist durch diese Merkmale für Patienten wesentlich komfortabler als ein Shaldonkatheter mit geraden Lumina. Der Patient bemerkt den Katheter nicht. Die Bewegungen des Kopfes werden nicht beeinträchtigt.
Die Langzeitstudie Studie von MC Weijmar u.a (NDT 2008 23; 977 - 983) belegt die überzeugenden Leistungsmerkmale des Raulerson Katheters während eines vierjährigen Beobachtungszeitraums, in welchem die Ergebnisse zusammengetragen und ausgewertet wurden.

medKomp

med-Komp GmbH
Römerstr. 15 · 45721 Haltern am See
Tel: 02364 / 92 99 35 · Mobil: 0177 / 630 86 75
Fax: 02364 / 50 60 853

www.med-komp.de

Original research article

JVA The Journal of Vascular Access

Precurved non-tunnelled catheters for haemodialysis are comparable in terms of infections and malfunction as compared to tunnelled catheters: A retrospective cohort study

The Journal of Vascular Access
2019, Vol. 20(3) 307–312

DOI: 10.1177/1129729818805954
journals.sagepub.com/home/jva


Mathijs van Oevelen[1], Alferso C Abrahams[1], Marcel C Weijmer[2], Tjerko Nagtegaal[1], Friedo W Dekker[3], Joris I Rotmans[4] and Sabine CA Meijvis[1]; on behalf of the DUCATHO study group

Abstract

Background: The main limitations of central venous catheters for haemodialysis access are infections and catheter malfunction. Our objective was to assess whether precurved non-tunnelled central venous catheters are comparable to tunnelled central venous catheters in terms of infection and catheter malfunction and to assess whether precurved non-tunnelled catheters are superior to straight catheters.

Materials and methods: In this retrospective, observational cohort study, adult patients in whom a central venous catheter for haemodialysis was inserted between 2012 and 2016 were included. The primary endpoint was a combined endpoint consisting of the first occurrence of either an infection or catheter malfunction. The secondary endpoint was a combined endpoint of the removal of the central venous catheter due to either an infection or a catheter malfunction. Using multivariable analysis, cause-specific hazard ratios for endpoints were calculated for tunnelled catheter versus precurved non-tunnelled catheter, tunnelled catheter versus non-tunnelled catheter, and precurved versus straight non-tunnelled catheter.

Results: A total of 1603 patients were included. No difference in reaching the primary endpoint was seen between tunnelled catheters, compared to precurved non-tunnelled catheters (hazard ratio, 0.91; 95% confidence interval, 0.70–1.19, $p = 0.48$). Tunnelled catheters were removed less often, compared to precurved non-tunnelled catheters (hazard ratio, 0.65; 95% confidence interval, 0.46–0.93; $p = 0.02$). A trend for less infections and catheter malfunctions was seen in precurved jugular non-tunnelled catheters compared to straight non-tunnelled catheters (hazard ratio, 0.60; 95% confidence interval, 0.24–1.50; $p = 0.28$) and were removed less often (hazard ratio, 0.41; 95% confidence interval, 0.18–0.93; $p = 0.03$).

Conclusion: Tunnelled central venous catheters and precurved non-tunnelled central venous catheters showed no difference in reaching the combined endpoint of catheter-related infections and catheter malfunction. Tunnelled catheters get removed less often because of infection/malfunction than precurved non-tunnelled catheters.

[1]Department of Nephrology and Hypertension, University Medical Center Utrecht, Utrecht, The Netherlands
[2]Department of Internal Medicine, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands
[3]Department of Clinical Epidemiology, Leiden University Medical Center, Leiden, The Netherlands
[4]Department of Nephrology, Leiden University Medical Center, Leiden, The Netherlands

Corresponding author:
Sabine CA Meijvis, Department of Nephrology and Hypertension, University Medical Center Utrecht, Utrecht, The Netherlands.
Email: s.c.a.meijvis@umcutrecht.nl

Keywords
Haemodialysis, infections, catheter, complications, vascular access

Date received: 10 May 2018; accepted: 18 September 2018

Introduction

Patients on maintenance haemodialysis require a reliable vascular access. Ideally, every haemodialysis patient should have a sufficiently matured arteriovenous fistula at the start of haemodialysis. However, maturation failure occurs in roughly one in three patients, while others have no suitable vessels to create a durable arteriovenous access due to pre-existing vascular pathology.[1] In addition, some patients develop a rapidly progressive kidney disease, which precludes timely planning for an arteriovenous access. For these reasons, 68% of patients in Europe initialize dialysis using a central venous catheter (CVC) for vascular access.[2] The use of CVCs among prevalent haemodialysis patients was 32% in 2009.[2]

A CVC has several disadvantages, with the risk of infection and catheter malfunction being the main challenges. Current guidelines recommend to remove the CVC in almost all catheter-related infections.[3,4] Furthermore, a CVC with catheter malfunction has to be removed eventually in most cases.[5–7] This is an important issue for patients dependent on a CVC for haemodialysis. Therefore, several recommendations are made to prevent loss of CVC. For example, the European Renal Best Practice guideline states that non-tunnelled central venous catheters (NTCVCs) should be avoided as much as possible, since the risk of infection compared to tunnelled central venous catheters (TCVCs) is even higher.[3] A possible explanation for this could be the lack of a cuff to act as a barrier against invasion of bacteria from the exit site into the systemic circulation. The literature on this subject, however, is of older age.[6,8] With the present-day hygiene measurements and the introduction of precurved NTCVCs inserted in the low jugular position, it is a subject of discussion whether these recommendations still hold true.

In this study, the primary objective was to assess whether precurved NTCVCs are comparable to TCVCs in terms of a combined endpoint of infection and catheter malfunction. Furthermore, we aimed to assess whether precurved NTCVCs are superior to straight NTCVCs for these adverse outcomes.

Materials and methods

Study design and population

This was a retrospective observational, multicentre cohort study in 12 participating hospitals in the Netherlands. The study was approved by the Medical Research Ethics Committee of the University Medical Center Utrecht. Data were collected from electronic patient records of the participating centres. From 1 January 2012 until 31 December 2016, all patients aged 18 years or older in whom a CVC for haemodialysis was inserted were included in this database. If a CVC was placed for continuous venovenous haemofiltration in the intensive care unit, if patients objected to use their medical record for research purposes or if patients underwent haemodialysis in a non-participating centre during the study period, they were excluded from the database. Follow-up for each CVC was recorded until removal, death or the end of the study period.

Use of immunosuppressive medication was defined as the use of any dose of glucocorticoids or any other recognized immunosuppressive medication during the period that the CVC was in situ. Acute start of dialysis was defined as haemodialysis starting without the patient previously receiving predialysis care, such as education and counselling at the outpatient clinic. All long-term patients were on a standard regimen of three (range, 2–4) dialysis sessions per week. Each hospital used their own protocol for catheter insertion and care; however, this always included ultrasound guidance, local anaesthesia and complete sterile barrier precautions during insertion and aseptic treatment during dialysis sessions by experienced dialysis nurses or nephrology staff. Catheters were exclusively used for haemodialysis.

In the current literature, there is no evidence that there are clinical relevant differences between individual catheter models within the different types of catheters (tunnelled, precurved or straight).[9–12] Therefore, we analysed the catheters as a group and not by each model separately.

Outcomes

Primary and secondary endpoints. The primary endpoint of the study was a combined endpoint consisting of the first occurrence of either a catheter-related infection (exit site, tunnel or systemic) or a catheter malfunction. The secondary endpoint was a combined endpoint consisting of the removal of the CVC due to either a catheter-related infection or a catheter malfunction.

Catheter-related infections. Infections were categorized into exit site infections, tunnel infections and systemic infections. Exit site infections were diagnosed if erythema, induration and/or pain near the insertion site of the CVC were present with positive cultures from secretions. Tunnel

Table 1. Baseline characteristics of enrolled patients.

	Total ($n = 1603$)
Age at placement of first CVC (years)	62.4 ± 15.7
Male sex	942 (58.8)
BMI (kg/m^2)	26.3 ± 5.4
Comorbidity	
Diabetes mellitus	582 (36.3)
Peripheral artery disease	209 (13.0)
Cerebrovascular disease	237 (14.8)
Medication	
Anticoagulants	637 (39.7)
Antiplatelet drugs	507 (31.6)
Immunosuppression	440 (27.4)
Dialysis characteristics	
Acute start (vs planned start)	640 (39.3)

CVC: central venous catheter; BMI: body mass index; SD: standard deviation.
Data are presented as mean ± SD or *n* (%).

infections were diagnosed if tenderness, induration and/or erythema of the skin and subcutaneous tissue were present along the insertion site and tunnelled route of the CVC, with positive cultures from secretions. Systemic infections were defined as the presence of positive blood cultures associated with clinical symptoms of infection, such as fever or raised inflammatory parameters. Patients were also considered as having a systemic infection when they had clinical signs of infection, without any other focus, and when the infection was treated as a bloodstream infection.

Catheter malfunction. Catheter malfunction was defined as absent or low haemodialysis blood flows that impaired effective haemodialysis delivery and required treatment, as indicated by the treating physician. This included thrombosis, catheter material problems or dysfunction due to other causes. Thrombosis was defined as a formed thrombus which attaches to the inner or outer surface of the catheter. Catheter material problem was defined as when catheters tore or hubs were dysfunctional. Potential treatments for catheter malfunction included use of thrombolytics such as urokinase, CVC guidewire exchange, radiologic intervention, catheter site abandonment or surgical intervention.

Statistical analysis

Data were stored in an SPSS database (version 21.0), and descriptive data were generated in SPSS. Multivariable analysis was performed in R Studio (version 3.2.2) with a Cox proportional hazards model. Cause-specific hazard ratios for our primary and secondary endpoint were calculated for TCVC versus NTCVC (both straight and precurved), for TCVC versus precurved NTCVC, and for precurved versus straight NTCVC. Since femoral catheters are more prone to infection than jugular catheters, we also compared both endpoints using only jugular catheters.[13–15] For each patient, all CVCs that were inserted during the study period were included in the database. However, for all analyses, we only used the first CVC included in this period and patients were censored after the first event, since consecutive events within patients are not independent. On theoretical grounds, age, sex, history of diabetes mellitus, cerebrovascular or peripheral vascular disease and catheter diameter were identified as potential confounders and entered in the model. Moreover, to correct for correlation of data from patients from the same hospitals, random effects for hospitals were included by fitting shared-frailty terms in the model. A Gaussian distribution of the frailty parameter was assumed. The proportional hazards assumption was verified with both formal tests and graphically, using Schoenfeld residuals. The Cox regression models were fitted with the '*cmprsk*', '*coxme*' and '*survival*' packages. Values of $p \leqslant 0.05$ were considered statistically significant.

Results

Patient and catheter characteristics

Over the 5-year period, we enrolled 1603 unique patients with a total of 2746 CVCs (median, 1 CVC per patient; interquartile range (IQR), 1–2) with a total of 145,008 catheter days. The baseline and dialysis characteristics of these patients are shown in Table 1. Mean age was 62 ± 16 years, and 59% of the patients were male. Median catheter days depended strongly on site of insertion and catheter type: 8 days (IQR, 5–11) for straight femoral catheters to 134 days (IQR, 49–260) for tunnelled jugular catheters. The rates of infections and catheter malfunction, divided by type of CVC and insertion place, are shown in Table 2. In 127 patients, another type of CVC was used, such as a tunnelled femoral catheter or a subclavian catheter.

Primary endpoint. After adjustment for potential confounders, the hazard ratio for the combined endpoint infection or catheter malfunction did not differ significantly between tunnelled and non-tunnelled catheters (hazard ratio (HR), 0.79; 95% confidence interval (CI), 0.62–1.00, $p = 0.05$), as shown in Table 3. In the NTCVCs, precurved catheters had significantly less infections and catheter malfunction than straight NTCVCs (HR, 0.56; 95% CI, 0.32–0.97; $p = 0.04$). When only using jugular catheters, this effect was similar but no longer statistically significant (HR, 0.60; 95% CI, 0.24–1.50; $p = 0.28$). No difference in reaching the primary endpoint was seen between TCVCs, compared to precurved NTCVCs (HR, 0.91; 95% CI, 0.70–1.19; $p = 0.48$). When only using jugular catheters, this effect was comparable.

Table 2. Catheter characteristics and adverse events, using the first catheter of each patient and first event of each catheter only.

	Tunnelled jugular	Precurved jugular	Straight jugular	Straight femoral
	(*n* = 391)	(*n* = 635)	(*n* = 210)	(*n* = 240)
Catheter days in place (median, IQR)	134 (47–259)	52 (17–118)	24 (10–56)	8 (5–10)
Total number of catheter days	74,059	53,438	10,260	2464
Length of catheter (cm)				
<20	4 (1.0)	593 (93.4)	170 (81.0)	18 (7.5)
20–24	134 (34.3)	33 (5.2)	21 (10.0)	137 (57.1)
⩾25	211 (54.0)	0 (0.0)	12 (5.7)	71 (29.6)
Diameter of catheter (French)				
<12	11 (2.8)	110 (17.3)	76 (36.2)	71 (29.6)
12–13.5	45 (11.5)	168 (26.5)	96 (45.7)	123 (51.3)
⩾14	312 (79.8)	301 (47.4)	22 (10.5)	31 (12.9)
Reason for removal				
Infection	65 (16.6)	57 (9.0)	20 (9.5)	9 (3.8)
Catheter malfunction	51 (13.0)	61 (9.6)	24 (11.4)	19 (7.9)
Infections (per 1000 catheter days)	1.13	1.82	2.34	3.25
Exit site	0.42	0.97	0.78	0.81
Tunnel	0.05	–	–	–
Systemic	0.66	0.84	1.56	2.44
Catheter malfunction (per 1000 catheter days)	1.70	2.99	4.97	15.83
Thrombosis	0.61	0.73	2.05	5.28
Material problem	0.11	0.30	0.78	0.81
Other or unknown	0.99	1.96	2.14	9.74

IQR: interquartile range; CVC central venous catheter.
Data are presented as *n* (%), unless otherwise specified. Numbers might not add up to the total because of missing values.

Table 3. Multivariable analysis.

	HR (95% CI)	*p* value
Primary endpoint		
TCVC vs NTCVC (ref.)	0.79 (0.62–1.00)	0.05
TCVC vs NTCVC (ref.), jugular only	0.79 (0.61–1.01)	0.06
Precurved vs straight CVC (ref.)	0.56 (0.32–0.97)	0.04
Precurved vs straight CVC (ref.), jugular only	0.60 (0.24–1.50)	0.28
TCVC vs precurved CVC (ref.)	0.91 (0.70–1.19)	0.48
TCVC vs precurved CVC (ref.), jugular only	0.85 (0.65–1.13)	0.26
Secondary endpoint		
TCVC vs NTCVC (ref.)	0.48 (0.34–0.66)	<0.01
TCVC vs NTCVC (ref.), jugular only	0.52 (0.36–0.74)	<0.01
Precurved vs straight CVC (ref.)	0.46 (0.24–0.88)	0.02
Precurved vs straight CVC (ref.), jugular only	0.41 (0.18–0.93)	0.03
TCVC vs precurved CVC (ref.)	0.65 (0.46–0.93)	0.02
TCVC vs precurved CVC (ref.), jugular only	0.66 (0.45–0.95)	0.02

HR, hazard ratio; CI confidence interval; CVC, central venous catheter; TCVC, tunnelled CVC; NTCVC, non-tunnelled CVC; ref, reference.
Corrected for age, sex, diabetes, cerebrovascular disease, peripheral vascular disease and catheter diameter. Random effects for hospitals were included by fitting shared-frailty terms in the model. Proportional hazards assumption not verified.

Secondary endpoint. The removal of the CVC because of infection or catheter malfunction occurred less often in TCVCs, compared to NTCVCs (HR 0.48, 95% CI 0.34–0.66, $p < 0.01$). In the NTCVCs, precurved catheters were removed less often than straight NTCVCs (HR 0.46, 95% CI 0.24–0.88, $p = 0.02$). When only assessing jugular CVCs, the hazard ratio remained comparable. TCVCs were removed less often, compared to precurved NTCVCs (HR, 0.65; 95% CI, 0.46–0.93; $p = 0.02$).

Sensitivity analysis. We conducted a sensitivity analysis by including acute start of dialysis in the multivariable model. This did not significantly change the occurrence of both primary and secondary endpoints (data not shown). Including

the insertion side of the CVC to the multivariable model also did not significantly change the occurrence of either endpoint (data not shown).

Discussion

The present study shows that TCVCs and precurved NTCVCs are comparable in terms of reaching the combined endpoint of catheter-related infections and catheter malfunction. This is an important observation because the most recent Kidney Disease Outcomes Quality Initiative (KDOQI) guideline recommends to use a TCVC in case a CVC for haemodialysis is needed for more than 1 week.[16] This guideline is of older age (2006), and the use of precurved catheters is not yet mentioned in this guideline. In previous observational studies, TCVCs were repeatedly associated with lower risk of infections compared to NTCVCs.[6,8] The NTCVCs in these studies were all straight CVCs. In our study, we show that straight NTCVCs have a higher risk of infections and catheter malfunction compared to precurved NTCVCs. This can explain the advantage of TCVCs over NTCVCs in the previous literature. Randomized controlled trials comparing TCVCs with precurved NTCVCs are lacking. In line with our current study, Weijmer et al.[17] showed in an observational trial in 2008 that precurved jugular NTCVCs had a lower risk of infection and less catheter malfunction than straight jugular NTCVCs. To our knowledge, this is the only study to compare these catheters.

TCVCs have a cuff that acts as a barrier against invasion of bacteria from the exit site into the systemic circulation. Moreover, TCVCs are usually 14–15 French in diameter, compared to 11–12 French in straight CVCs, leading to less catheter malfunction. Our study confirms that TCVCs are indeed less prone to infections and catheter malfunction than straight CVCs.

There are several explanations as to why precurved catheters cause less infections compared to straight NTCVCs. Fixation of straight jugular NTCVCs is more difficult and head and neck movements are limited. Discomfort, due to this limited movement, and inadequate fixation lead to more manipulation of the catheter through the exit site, which can easily cause laceration of the skin and secondary infection of the exit site, a well-known risk factor for catheter-related bloodstream infections.[13] Furthermore, straight jugular catheters have an upward directed exit site, contrary to precurved catheters inserted low in the jugular vein, in which the exit site is directed downward. In catheters for peritoneal dialysis, an upward exit site is a well-known risk factor for exit site infections and peritonitis.[18] Our finding that precurved non-tunnelled catheters have a comparable incidence of infections and catheter malfunction compared to TCVCs can possibly be explained by the fact that the exit site is downward and therefore causes fewer infections. Also, the most frequently used precurved catheters in our study are 15.5 French, the same diameter as most TCVCs, leading to a better flow and therefore less catheter malfunction.

Another finding of our study is that TCVCs are removed less often because of infections or catheter malfunctions compared to precurved NTCVCs. The difference between our primary and secondary endpoint regarding tunnelled and precurved CVCs may reflect the clinical practice in which the removal or replacement of a TCVC is much more complicated than in a precurved catheter. Inserting a new TCVC requires more expertise of the operator and a prolonged procedure time. Also, NTCVCs can easily be replaced over a guidewire. This possibly results in more frequent removal of NTCVCs compared to TCVCs.

Guidelines focus on the prevention of catheter-related infections. However, in our study, catheter malfunction occurred more frequently than catheter-related infections and led to comparable incidence of catheter removal. Due to low number of events, we did not analyse both outcomes separately.

A major limitation of our study is its retrospective design. Although potential patient and centre-related confounders were accounted for by using multivariable analysis, we cannot exclude that there is remaining confounding by indication, especially when comparing NTCVCs with TCVCs. In the case of acute need for dialysis, NTCVC placement will often be chosen over TCVC placement as it is a less challenging and invasive procedure and renal function recovery might occur. This could result in less comparable patient groups. However, in our sensitivity analysis, adding the acute start of dialysis to the multivariable analysis did not change any of the endpoints.

A possible limitation could be the recent rise in popularity of precurved NTCVCs, as we did not correct for time-dependent improvements in dialysis care, such as catheter care protocols. This effect, however, will probably be negligible as the use of precurved NTCVCs in our study only increased from 37.5% in 2012 to 41.3% in 2016.

In our study, precurved catheters were in place for a median of 52 days (IQR, 17–118) compared to 134 days (IQR 47–259) for TCVCs. As previous studies have shown, the risk of catheter-related infections decreases over time.[5,8,17] It is unclear whether our observation of TCVCs and precurved NTCVCs having a comparable occurrence of the combined endpoint of catheter-related infections and catheter malfunction still holds beyond this period.

In conclusion, this study demonstrates that precurved non-tunnelled dialysis catheters are comparable to tunnelled catheters in terms of catheter-related infections and catheter malfunction. Precurved NTCVCs are increasingly used in daily dialysis practice probably because they have several advantages over tunnelled catheters. Given these findings, a randomized controlled trial comparing precurved non-tunnelled and tunnelled catheters is warranted

to analyse whether precurved non-tunnelled catheters are indeed non-inferior to tunnelled catheters.

Acknowledgements

A.A., J.R. and S.M. designed the study. M.O. and T.N. acquisitioned the data. M.O. and S.M. analysed the data. F.D. supervised the statistical analysis. M.O., M.W. and S.M. wrote the manuscript. All authors discussed and commented on the final manuscript. DUCATHO study group collaborators: J.A. Bijlsma (Dianet, Amsterdam, The Netherlands), K.E.A. van der Bogt (Haaglanden Medical Center, Den Haag, The Netherlands), A. van de Brug (University Medical Center Utrecht, Utrecht, The Netherlands), C.E. Douma (Spaarne Gasthuis, Hoofddorp, The Netherlands), E.J. Hoorn (Erasmus Medical Center, Rotterdam, The Netherlands), D.H.T. IJpelaar (Groene Hart Hospital, Gouda, The Netherlands), M.J. Krol-van Straaten (HagaZiekenhuis, Den Haag, The Netherlands), K.W. Mui (Hospital St. Jansdal, Harderwijk, The Netherlands), J.H.M. Tordoir (Maastricht University Medical Center, Maastricht, The Netherlands), H.H. Vincent (St. Antonius Hospital, Nieuwegein, The Netherlands), N. Zonnebeld (Maastricht University Medical Center, Maastricht, The Netherlands)

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was funded by the Dutch Kidney Foundation (grant A2D5P02). The funders played no role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

References

1. Bylsma LC, Gage SM, Reichert H, et al. Arteriovenous fistulae for haemodialysis: a systematic review and meta-analysis of efficacy and safety outcomes. *Eur J Vasc Endovasc Surg* 2017; 54(4): 513–522.
2. Noordzij M, Jager KJ, Van Der Veer SN, et al. Use of vascular access for haemodialysis in Europe: a report from the ERA-EDTA registry. *Nephrol Dial Transplant* 2014; 29(10): 1956–1964.
3. Vanholder R, Canaud B, Fluck R, et al. Diagnosis, prevention and treatment of haemodialysis catheter-related bloodstream infections (CRBSI): a position statement of European Renal Best Practice (ERBP). *NDT Plus* 2010; 3(3): 234–246.
4. Mermel LA, Allon M, Bouza E, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 update by the Infectious Diseases Society of America. *Clin Infect Dis* 2009; 49(1): 1–45.
5. Little MA, O'Riordan A, Lucey B, et al. A prospective study of complications associated with cuffed, tunnelled haemodialysis catheters. *Nephrol Dial Transplant* 2001; 16(11): 2194–2200.
6. Thomson P, Stirling C, Traynor J, et al. A prospective observational study of catheter-related bacteraemia and thrombosis in a haemodialysis cohort: univariate and multivariate analyses of risk association. *Nephrol Dial Transplant* 2010; 25(5): 1596–1604.
7. Xue H, Ix JH, Wang W, et al. Hemodialysis access usage patterns in the incident dialysis year and associated catheter-related complications. *Am J Kidney Dis* 2013; 61(1): 123–130.
8. Weijmer MC, Vervloet MG and Ter Wee PM. Compared to tunnelled cuffed haemodialysis catheters, temporary untunnelled catheters are associated with more complications already within 2 weeks of use. *Nephrol Dial Transplant* 2004; 19(3): 670–677.
9. Oliver MJ. Acute dialysis catheters. *Semin Dial* 2001; 14(6): 432–435.
10. Van Der Meersch H, De Bacquer D, Vandecasteele SJ, et al. Hemodialysis catheter design and catheter performance: a randomized controlled trial. *Am J Kidney Dis* 2014; 64(6): 902–908.
11. O'Dwyer H, Fotheringham T, O'Kelly P, et al. A prospective comparison of two types of tunneled hemodialysis catheters: the Ash Split versus the PermCath. *Cardiovasc Intervent Radiol* 2005; 28(1): 23–29.
12. Richard HM 3rd, Hastings GS, Boyd-Kranis RL, et al. A randomized, prospective evaluation of the Tesio, Ash split, and Opti-flow hemodialysis catheters. *J Vasc Interv Radiol* 2001; 12(4): 431–435.
13. Oliver MJ, Callery SM, Thorpe KE, et al. Risk of bacteremia from temporary hemodialysis catheters by site of insertion and duration of use: a prospective study. *Kidney Int* 2000; 58(6): 2543–2545.
14. Marik PE, Flemmer M and Harrison W. The risk of catheter-related bloodstream infection with femoral venous catheters as compared to subclavian and internal jugular venous catheters: a systematic review of the literature and meta-analysis. *Crit Care Med* 2012; 40(8): 2479–2485.
15. Lemaire X, Morena M, Leray-Moragues H, et al. Analysis of risk factors for catheter-related bacteremia in 2000 permanent dual catheters for hemodialysis. *Blood Purif* 2009; 28(1): 21–28.
16. National Kidney Foundation. KDOQI clinical practice guidelines and clinical practice recommendations for 2006 updates: hemodialysis adequacy, peritoneal dialysis adequacy and vascular access. *Am J Kidney Dis* 2006; 48(Suppl.1): S1–S322.
17. Weijmer MC, Vervloet MG and Ter Wee PM. Prospective follow-up of a novel design haemodialysis catheter; lower infection rates and improved survival. *Nephrol Dial Transplant* 2008; 23(3): 977–983.
18. Golper TA, Brier ME, Bunke M, et al. Risk factors for peritonitis in long-term peritoneal dialysis: the Network peritonitis and catheter survival studies. Academic subcommittee of the steering committee of the network peritonitis and catheter survival studies. *Am J Kidney Dis* 1996; 28(3): 428–436.

Prospective follow-up of a novel design haemodialysis catheter; Lower infection rates and improved survival

Article *in* Nephrology Dialysis Transplantation · March 2008

DOI: 10.1093/ndt/gfm767 · Source: PubMed

3 authors:

Marcel C Weijmer
St. Lucas Andreas Hospital
25 PUBLICATIONS **929** CITATIONS

SEE PROFILE

Marc G Vervloet
Amsterdam University Medical Center
226 PUBLICATIONS **5,876** CITATIONS

SEE PROFILE

Pieter ter Wee
Amsterdam University Medical Center
418 PUBLICATIONS **13,651** CITATIONS

SEE PROFILE

Nephrol Dial Transplant (2008) 23: 977–983
doi: 10.1093/ndt/gfm767
Advance Access publication 5 November 2007

Original Article

NDT
Nephrology Dialysis Transplantation

Prospective follow-up of a novel design haemodialysis catheter; lower infection rates and improved survival

Marcel C. Weijmer, Marc G. Vervloet and Piet M. ter Wee

Department of Nephrology, Vrije Universiteit Medical Center, Amsterdam, The Netherlands

Abstract

Background. Untunnelled straight jugular catheters (USC) are uncomfortable for patients and cannot be well fixated. This could be a reason for the high incidence of catheter-related complications.

Methods. We prospectively analysed the outcome of a novel designed untunnelled precurved catheter (UPC) with better fixation properties and compared it with the outcome of USC. The outcome was also related to data on tunnelled cuffed catheters (TCC).

Results. The outcome of USC was documented over a 32-month period. Thereafter, we switched to an UPC. The same catheter care protocol was used and not changed over time. A total of 104 USC and 65 UPC were inserted. Compared to USC, less UPC had to be removed for a complication (53 versus 15%; $P < 0.001$) and less periods of catheter-related bacteraemia were observed in UPC compared to USC [0 versus 5.6 per 1000 catheter days (cd); $P < 0.01$]. Removal for flow problems was similar. Compared to 64 TCC, inserted in the same period, UPC had more flow problems. Other outcomes and complication rates were similar. Complication rates for TCC inserted before and after the switch from USC to UPC were similar.

Conclusions. UPC have better patency rates and a lower risk for bacteraemia and exit-site infection compared to USC.

Keywords: Bacteraemia; catheter; clinical study; comparison; haemodialysis; infection; outcome; patency; precurved; temporary; tunnelled cuffed; untunnelled; vascular access

Introduction

Temporary untunnelled haemodialysis catheters for vascular access are regularly used in haemodialysis practice. Today, the preferred site for a temporary catheter is the jugular vein. Untunnelled catheters are often left in place for a prolonged period of time, despite the recommendation in the recently updated NKF-DOQI guidelines to use tunnelled cuffed catheters (TCC) whenever it can be anticipated that a catheter will be needed for >3 weeks [1]. This is probably because inserting TCC requires more experience, prolonged procedure time and special skills of the operator.

In incident haemodialysis patients, 48% of catheters in the United States and 75% of catheters in Europe are untunnelled and even in prevalent patients over a third of all catheters are untunnelled [2]. It has been shown that catheter-related complications are higher for temporary untunnelled jugular catheters compared to tunnelled catheters [3,4]. The reasons for these increased rates are not clear. It is suggested that poor fixation could be largely responsible. Current models of untunnelled straight jugular vein catheters (USC) are placed in the external or internal jugular vein pointing upward from the place of insertion. They are fixated cranial from the point of insertion and either have curved extensions (Figure 1A) or are curved laterally. These catheters are uncomfortable for the patient and can easily dislocate. In addition, on connection to the haemodialysis machine, pulling lines can kink the catheter or cause laceration of the exit site, a known risk factor for infection [5,6].

Recently, a novel designed untunnelled precurved temporary jugular catheter (UPC) model has become available (Duoflow®, Medcomp, Harleysville, USA). Inserted close to the upper border of the clavicle with the catheter bending over the clavicle and fixated to the chest wall, this catheter is more comfortable for patients (Figure 1B). During haemodialysis treatment, movement of this catheter is minimal.

The primary aim of this study was to compare the patency and catheter-related complications of this UPC with USC. We also related the results to the outcome of TCC during this study.

Subjects and methods

Patients and data collection

We analysed all untunnelled temporary jugular and tunnelled cuffed haemodialysis catheters inserted in the jugular

Correspondence and offprint requests to: M. C. Weijmer, Department of Nephrology, Sint Lucas Andreas Hospital, PO Box 9243, 1006 AE Amsterdam, The Netherlands. Tel: +31-205108911; Fax: +31-206837720; Email: mc.weijmer@weijmer.nl

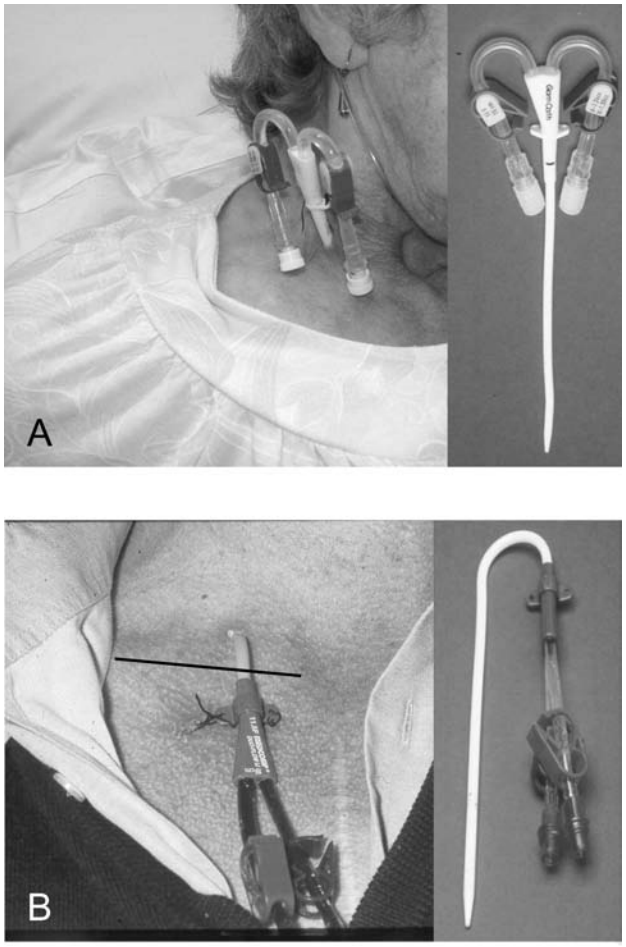


Fig. 1. Straight untunnelled jugular catheter (**A**) and the novel precurved untunnelled catheter (**B**). Catheters were inserted in the internal jugular vein about 1 cm above the clavicle (black line), low in the sternocleidomastoid triangle. A standard Seldinger guidewire procedure was used to introduce the catheter. Care was taken to insert the catheter including the first half of the curve. After insertion, the exit site should point forward to downward.

vein at the dialysis department of an academical teaching hospital over a 4-year period. On average, 60 haemodialysis patients are treated in our unit, 10% are patients with acute renal failure and 25% of patients depend on a catheter for vascular access. Data on all inserted catheters and catheter-related complications at follow-up were entered prospectively in a computerized patient data system by the attendant nephrologist and dialysis nursing team.

The decision on the type of catheter and place of insertion was left to the physician responsible for the patients' care at the time of insertion. In general, TCC were more likely to be chosen whenever it could be foreseen that a catheter was needed for >4 to 6 weeks. When this could not be determined or the need for a catheter was expected to be shorter, an untunnelled jugular catheter could be inserted.

Reasons for catheter removal were entered in the database: elective removal, exit-site infection, catheter-related bacteraemia (CRB), flow problems, accidental removal or catheter fracture. Catheters were evaluated for the type, place of insertion, time of insertion, duration of use and reason for removal. Femoral catheters were excluded. All cultures of blood and exit sites taken from the patient during the period when a catheter was in place were collected from the computerized data system of the department of microbiology. Baseline patient characteristics and demographical data were collected at the time of insertion. In addition, hospitalization for non-catheter-related reasons at any time when a catheter was in place and nasal staphylococcal aureus carrier was documented. Data on two catheters (both USC) were lost to follow-up shortly after insertion, because of transferral of the patient to another dialysis centre. These were excluded from the analysis.

Catheters, catheter care protocol and catheter outcome assessment

From 1 January 1997 to 1 September 1999, we used an untunnelled dual lumen 11 Fr polyurethane catheter with curved extensions (Gamcath®, Hechingen, Germany; $n = 89$) and dual lumen 11.5 Fr polyurethane catheter with curved extensions (Mahurkar, Tyco, Mansfield, MA, USA; $n = 15$) for the jugular site (Figure 1A). The outcome of these catheters has been described in our previous study [3]. After this period, we switched to a novel design untunnelled dual lumen polyurethane catheter (11.5 Fr; Duo-Flow® IJ, Medcomp, Harleysville, USA) (Figure 1B). For TCC we used Neostar Circle-C® (13.5 Fr; cuffed silicon, Horizon Medical Products, Atlanta, GA, USA; $n = 48$), PermCath® cuffed silicon (16 Fr; Tyco, Mansfield, MA, USA; $n = 5$), Tesio twin-cath® cuffed silicon (10 Fr; $n = 3$) and Ash-split® cuffed polyurethane (14.5 Fr; both Medcomp; $n = 8$).

All catheters were inserted under local anaesthesia and strict asepsis, and sutured to the skin. All untunnelled and tunnelled cuffed catheters were inserted after cannulation of the internal jugular vein close to (about 1 cm above) the clavicle, low in the sternocleidomastoid triangle in accordance with the puncture technique described by Rao *et al.* [7]. A standard Seldinger guidewire procedure was used to introduce the catheter. Care was taken to insert the catheter including the first half of the curve. After insertion, the exit site should point forward to downward. Ultrasound guidance was used whenever considered necessary.

Catheters were only handled by experienced dialysis nurses or nephrology staff, using sterile gloves and masks. The semi-occlusive dressings we used for exit-site care were inspected at every dialysis session and changed at least once a week, the exit site being cleansed with a povidone–iodine solution. Before removing the caps, the catheter hubs were disinfected with a chlorhexidine solution (2.5%). After dialysis treatment, catheters were locked with unfractionated heparin (5000 U/ml) with a volume equivalent to the internal volume of the lumen noted on the catheter. Catheters were used for haemodialysis exclusively.

CRB was defined as fever (temperature >38°C) or cold chills not during a dialysis treatment, with at least one positive blood culture and no other obvious cause of infection. In patients who developed signs of bacteraemia without symptoms of an alternative source other than the catheter, at least two blood cultures were taken either from the catheter or from a peripheral vein. Subsequently, antibiotics for

suspected CRB were given. When a CRB was established, the catheter was left in place in stable patients in whom fever disappeared after initiation of antibiotic treatment. In patients not improving within 48 h or with recurrent bacteraemia within 3 weeks after stopping antibiotic treatment, the catheter was removed. The policy was not different between untunnelled catheters and TCC at our institution in the study period. In the case of recurrent bacteraemia, only the first period was counted for the analysis.

Exit-site infection was defined as the development of a purulent exudate or redness around the site not resulting from residual stitches. After culturing, antibiotic treatment was recommended for at least 2 weeks. In the case of no improvement, the catheter had to be removed.

Flow problems In accordance with national guidelines, the minimal acceptable Qb was 200 ml/min and the target was 250 ml/min. More important, the minimal acceptable dialysis dose was a urea Kt/V of at least 1.2 per treatment. When this could not be reached, the flow or dialysis duration could be increased. When a persistent inability to run a blood flow of >200 ml/min occurred despite positional changes of the patient and/or additional flushing, urokinase 10 000 IU/ml was installed in both pools with a volume equivalent to the internal volume of the lumen. After 15 min the urokinase was withdrawn. If a blood flow of >200 ml/min was not achieved after this procedure, 100 000–250 000 IU of urokinase could be infused in 3 h during dialysis according to the protocol of Twardowski [8]. When this was not successful, the catheter was removed or exchanged.

No patient started coumarines because of flow problems.

Statistical analysis

Statistical analysis was performed with SPSS software 11.2 (SPSS Inc., Chicago, IL, USA). Non-parametric tests for two (Mann–Whitney *U* test) and multiple continuous variables (Kruskal–Wallis test) were used. For comparing binary and categorical variables, Chi-square and Fisher's exact tests were applied where appropriate. ANOVA was used to compare age and time on dialysis between multiple groups. Kaplan–Meier survival curves were constructed to analyse the patency rates and infectious complications. Functional catheters at the end of the observation time and catheters removed because they were no longer needed were analysed as censored values. The log rank test was used to compare groups and identify individual risk factors associated with a premature removal or catheter-related infection. At an individual two-sided P value of <0.1, the factor was included to fit a Cox-regression model. We used a forward stepwise conditional technique to identify the factors independently associated with catheter failure and infection. Differences were considered statistically significant for $P < 0.05$.

Results

A total of 233 haemodialysis catheters [14 434 catheter days (cd)] were included in the final analysis. There were 104 USC, 65 UPC and 64 TCC inserted.

Patient and catheter characteristics are given in Table 1. There were no statistical differences between USC and UPC. Patients who had a TCC inserted differed importantly from UC; patients with a TCC were more likely to be on chronic haemodialysis treatment, hospitalized, on coumarines and have diabetes diagnosed as primary cause for end-stage renal disease.

Patient and catheter characteristics of TCC inserted before ($n = 31$) and after ($n = 33$) the switch from USC to UPC were similar. Most catheters were right sided (87%). Since there was no significant difference in the outcome between catheters inserted in the right or left jugular vein, they were not separated in the definite analysis.

Catheter outcomes

Of 65 UPC inserted, 55 (85%) could be used until they were no longer needed compared to only 49 (47%) of 104 USC (relative risk for premature removal 0.22; 95% CI 0.11–0.44; $P < 0.001$). We experienced no episodes of pneumothorax on insertion. In 11 USC and 5 UPC insertions the carotid artery was accidentally punctured; no major bleeding was experienced. The rate of premature removal was reduced from 17.1 to 4.3 per 1000 cd after switching from USC to UPC.

Characteristics of premature removals are shown in Table 2. There was a reduction of 11.5 to 0 removals for catheter-related infections per 1000 cd after switching from USC to UPC ($P < 0.01$). However, removals for flow problems were similar (5.0 versus 4.3 per 1000 cd; $P = 0.27$). Log rank analysis of the risk for premature removal showed better rates for UPC compared to the USC group ($P < 0.0001$, Figure 2)

TCC were characterized by less premature removal rates compared to both untunnelled catheter groups. The risk for premature removal of TCC inserted before and after the switch from USC to UPC was not statistically different (relative risk 1.33; 95% CI 0.55–3.26; $P = 0.52$, Table 3, Figure 4).

Infectious complications

In patients with a UPC inserted, no episodes of CRB occurred. One catheter was instantly removed in an immunocompromised patient who presented with fever. However, an alternative diagnosis was made during the follow-up.

There was a reduction of CRB episodes after switching from USC to UPC (5.6 to 0 per 1000 cd; $P < 0.05$ by log rank testing) (Figure 3). Differences in CRB and exit-site infection rates within the catheter groups are presented in Table 2. The risk for CRB and exit-site infection in the TCC group during both periods was equal (relative risk 1.01; 95% CI 0.47–2.17; $P = 0.97$)

In 42% of cases, cultures yielded gram-positive micro-organisms, predominantly *Staphylococcus aureus* or *Staphylococcus epidermidis*, in 34% it concerned gram-negative micro-organisms. The remaining cultures revealed multiple micro-organisms or yeasts.

Table 1. Base line characteristics of the patients and catheters

Characteristics	Untunnelled catheters		Tunnelled cuffed catheters ($n = 64$)
	Straight ($n = 104$)	Precurved ($n = 65$)	
Catheter days (no.)	3209	2101	9124
Time left in place (days (mean range))			
All catheters	31 (2–162)	32 (5–232)	142 (7–604)
Uncomplicated catheters	30 (2–132)	32 (5–232)	146 (13–568)
More than three months (%)	6	3	52
Right-sided insertion (%)	84	91	88
Age (mean ± SD)	61.0 ± 13.8	58.7 ± 16.4	58.7 ± 14.7
Race			
Caucasian (%)	71	72	72
Black (%)	18	20	19
Other (%)	11	8	9
Male sex (%)	66	59	53
Yr on dialysis (mean ± SD)	1.2 ± 2.1*	1.3 ± 2.2	2.1 ± 2.5*
Cause of end stage renal disease			
Diabetes (%)	24*	11*	27*
Renovascular (%)	20	11	11
Polycystic disease (%)	8	11	14
Glomerulonephritis (%)	13	22	17
HIV (%)	1	2	1
other (%)	24	28	24
unknown (%)	10	15	6
Acute renal failure (%)	38**	29**	9**
Diabetes mellitus (%)	27	19	30
Cardiovascular disease (%)			
Coumarin use (%)	8‡	17	23‡
Immune suppression (%)	14	17	9
Malignancy (%)	9	3	5
Staphylococcus Aureus carrier (%)	48	45	44

Abbreviations: SD, standard deviation.
*$P < 0.05$.
**$P < 0.01$.
‡$P < 0.01$.

Table 2. Summary of premature removals and catheter-related complications

Variable	Untunnelled catheters		Relative risk (95% confidence interval)
	Straight ($n = 104$) No. of events (%)	Precurved ($n = 65$)	
Premature removal			
For any complication	55 (53)	10 (15)	0.22 (0.11–0.44); $P < 0.0001$
No. per 1000 catheter days	17.1	4.8	
For any infection	37 (36)	0	0.02 (0.01–0.33); $P = 0.006$
No. per 1000 catheter days	11.5	0	
For flow problems	16 (15)	9 (14)	0.56 (0.20–1.58); $P = 0.27$
No. per 1000 catheter days	5.0	4.3	
For fracture/accidental removal/other	2 (2)	1 (2)	
No. per 1000 catheter days	0.6	0.5	
Catheter-related bacteraemia	18 (17)	0	0.02 (0.01–0.97); $P = 0.048$
No. per 1000 catheter days	5.6	0	
Exit-site infection	32 (31)	0	0.04 (0.01–0.29); $P = 0.002$
No. per 1000 catheter days	10.0	0	

Discussion

Our study demonstrates that a novel design forward-bended precurved haemodialysis catheter inserted in the low jugular site has a better survival and lower risk of infection than a straight jugular catheter.

There are some possible explanations for these findings. In the present study the reduction of exit-site infections for UPC (0 per 1000 cd) compared to USC (10 per 1000 cd) was remarkable and this probably partially explained the reduction in CRB. An important problem of USC is that an adequate fixation is difficult and that they are

uncomfortable for the patient because neck and head movements are limited. Inadequate fixation and discomfort leads to more manipulation, sliding of the catheter through its port and can easily give laceration and secondary infection of the exit site. These are well-known risk factors for subsequent CRB [9,10]. In addition, straight jugular catheters have an upward directed exit site. In peritoneal dialysis catheters, this is a well-established risk factor for exit-site infections and peritonitis [5,6]. Probably, with an upward directed exit site, adequate drainage of debris is prohibited and colonization of the catheter exit site promoted, which can cause local infection and subsequent systemic infection. Therefore, in peritoneal dialysis catheter management, a downward directed exit site is recommended.

Exit-site colonization can also lead to catheter hub colonization and subsequent bacteraemia. This could also be an explanation for the differences found in this study, but as regular cultures of the hub were not performed, this remains speculative. The same reduction of colonization and infections in exit sites that permit an adequate drainage could also be the reason that in recent studies, USC had higher rates of infectious complications compared to untunnelled subclavian catheters [3,4]. The UPC used in this study has the advantage of a forward to downward directed exit site that makes adequate drainage of debris possible. The improved fixation properties and exit-site direction are probably the most important explanation for the reduction of infection rates in UPC compared to USC. As overall outcome between UPC and TCC was not different, UPC can be an attractive alternative for the time period studied. The low rates of infectious complications in UPC compared to

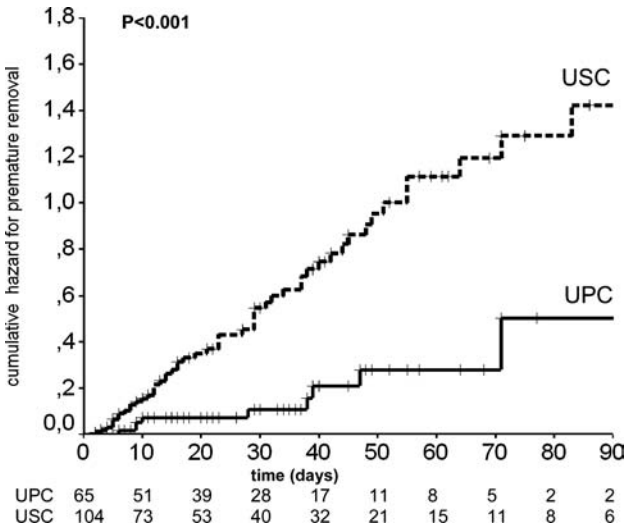


Fig. 2. Kaplan–Meier curves of cumulative hazard for premature removal for untunnelled precurved jugular catheters (UPC) (—) compared to untunnelled straight jugular catheters (USC) (——) ($P < 0.001$ by log rank statistics). Tick marks indicate censored catheters. Numbers of catheters at risk for any time period are given.

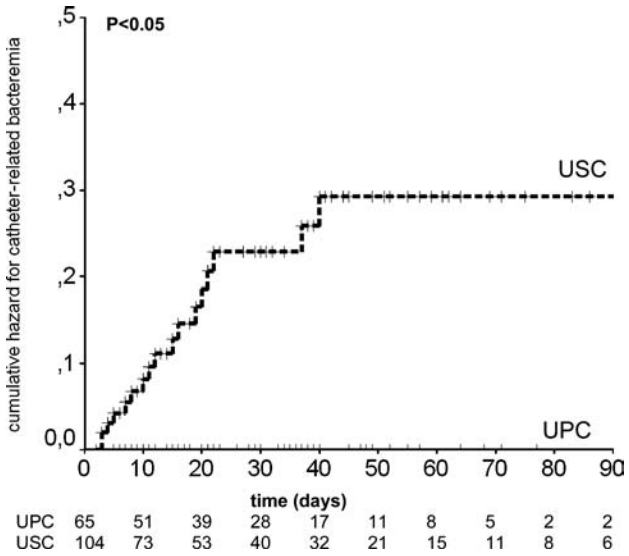


Fig. 3. Kaplan–Meier curves of cumulative hazard for catheter-related bacteraemia for untunnelled precurved jugular catheters (UPC) (—) compared to untunnelled straight jugular catheters (USC) (——) ($P < 0.05$ by log rank statistics). Tick marks indicate censored catheters. Numbers of catheters at risk for any time period are given.

Table 3. Summary of premature removals and catheter-related complications in TCC during the period USC were inserted (first period) and UPC were inserted (second period)

	Tunnelled cuffed catheters		
	First period ($n = 31$)	Second period ($n = 33$)	
Catheter days Variable	5216 No. of events (%)	3908	Relative risk (95% confidence interval)
Premature removal			
For any complication	11 (35)	11 (33)	1.33 (0.55–3.26); $P = 0.52$
No. per 1000 catheter days	3.3	2.8	
For any infection	6 (19)	5 (15)	ns
No. per 1000 catheter days	1.2	1.3	
For flow problems	3 (10)	4 (12)	ns
No. per 1000 catheter days	0.6	1.0	
For fracture/accidental removal/other	2 (6)	2 (6)	ns
No. per 1000 catheter days	0.4	0.5	
Catheter-related bacteraemia	2 (6)	3 (8)	ns
No. per 1000 catheter days	0.4	0.8	
Exit-site infection	4 (8)	2 (6)	ns
No. per 1000 catheter days	0.8	0.5	

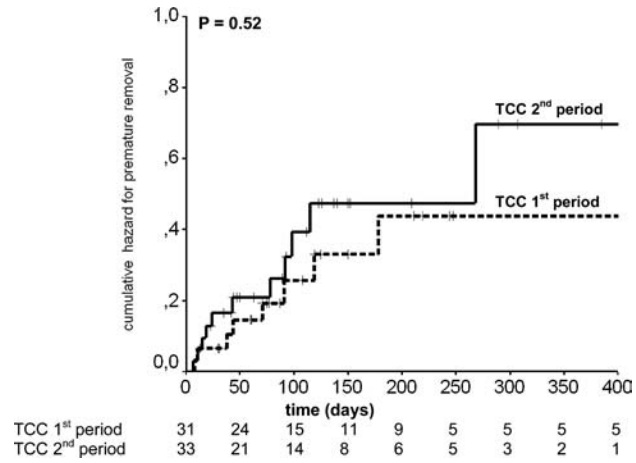


Fig. 4. Kaplan–Meier curves of cumulative hazard for premature removal for tunnelled cuffed catheters (TCC) in the first period (——) compared to the second period (—) of the study ($P = 0.52$ by log rank statistics). Tick marks indicate censored catheters. Numbers of catheters at risk for any time period are given.

TCC might have been influenced by the shorter period UPC were left in place compared to TCC.

There are limitations to our study. The prospective sequential cohort analysis of the USC and UPC respectively, instead of a randomized design, could have led to bias due to unnoticed differences in time, not accounted for by baseline characteristics. Furthermore, the propensity for inserting a TCC instead of an untunnelled catheter might have changed over time. However, since outcome in TCC in the two time periods did not change, this probably did not influence the results. Also, the analysis between untunnelled catheters on one hand and TCC on the other might be biased due to lack of randomization and differences in indication.

We observed differences in baseline characteristics between TCC and UPC, like the presence of diabetes and the incidence of acute renal failure. Despite the fact that we corrected for these differences in the outcome analysis, patients with a TCC are different to patients with a UC and a direct comparison is hazardous.

Another confounding factor in catheter studies influencing the outcome of catheters is the catheter care protocol. It has been shown in randomized studies that the risk for CRB can be reduced with a thorough protocol [15,16]. In our study, catheter care protocol was not changed over the entire observation period and the incidence of catheter-related infections of TCC in the time periods when USC (first period) or UPC (second period) were used, was not statistically different making a time bias and differences in catheter care as explanation for our findings unlikely.

Previous studies in tunnelled catheters have suggested that catheter-related complications, especially infections, are constant over time or tend to decrease [3,11,12]. Furthermore, as shown in the choice study, few patients will need a catheter for >3 months [13]. Considering catheter-related infections as a major drawback for catheter use, our results show that an UPC for the period of 3 months could be a safe option, more convenient for the patient and physician during insertion and probably cost-saving. This is in contrast with the NKF-DOQI guidelines, which state that a tunnellized catheter should be used whenever it can be foreseen that a catheter is needed for >2 to 4 weeks [1]. However, these guidelines are predominantly expert based or supported by studies with USC including our own [3,4].

Compared to TCC, more UPC had to be removed for flow problems. This was probably caused by the fact that TCC have a 2–3 Fr larger diameter and the flow resistance is proportional to the diameter of a catheter to the fourth power. Therefore, it is clear that flow characteristics are better in TCC and that there is more flow reserved in the case of partial obstruction. The function of UPC can probably be improved by increasing its diameter and tip construction [14].

In conclusion, our study demonstrates that in addition to improved patient comfort, an untunnelled precurved jugular haemodialysis catheter has better patency rates and a lower risk for infection compared to a straight jugular catheter with curved extensions. This novel design precurved catheter placed in the lower jugular position should be preferred as the untunnelled jugular catheter model over straight models with curved extensions and can be used safely when it can be foreseen that a catheter is needed for up to 3 months. Our results make a prospective randomized trial comparing TCC to UPC with a wider inner diameter an important issue for the future.

Conflict of interest statement. None declared.

References

1. NKF-K/DOQI Clinical practice guidelines for vascular access: update. 2000. *Am J Kidney Dis* 2001; 37: S137–S181
2. Pisoni RL, Young EW, Dykstra DM *et al*. Vascular access use in Europe and the United States: results from the DOPPS. *Kidney Int* 2002; 61: 305–316
3. Weijmer MC, Vervloet MG, ter Wee PM. Compared to tunnelled cuffed haemodialysis catheters, temporary untunnelled catheters are associated with more complications already within 2 weeks of use. *Nephrol Dial Transplant* 2004; 19: 670–677
4. Kairaitis LK, Gottlieb T. Outcome and complications of temporary haemodialysis catheters. *Nephrol Dial Transplant* 1999; 14: 1710–1714
5. Warady BA, Sullivan EK, Alexander SR. Lessons from the peritoneal dialysis patient database: a report of the north American pediatric renal transplant cooperative study. *Kidney Int Suppl* 1996; 53: S68–S71
6. Golper TA, Brier ME, Bunke M *et al*. Risk factors for peritonitis in long-term peritoneal dialysis: the network 9 peritonitis and catheter survival studies. Academic subcommittee of the steering committee of the network 9 peritonitis and catheter survival studies. *Am J Kidney Dis* 1996; 28: 428–436
7. Rao TL, Wong AY, Salem MR. A new approach to percutaneous catheterization of the internal jugular vein. *Anesthesiology* 1977; 46: 362–364
8. Twardowski ZJ. High-dose intradialytic urokinase to restore the patency of permanent central vein hemodialysis catheters. *Am J Kidney Dis* 1998; 31: 841–847
9. Mermel LA. Prevention of intravascular catheter-related infections. *Ann Intern Med* 2000; 132: 391–402
10. Oliver MJ, Callery SM, Thorpe KE *et al*. Risk of bacteremia from temporary hemodialysis catheters by site of insertion and duration of use: a prospective study. *Kidney Int* 2000; 58: 2543–2545

11. Little MA, O'Riordan A, Lucey B *et al*. A prospective study of complications associated with cuffed, tunnelled haemodialysis catheters. *Nephrol Dial Transplant* 2001; 16: 2194–2200
12. Lund GB, Trerotola SO, Scheel PFJ *et al*. Outcome of tunneled hemodialysis catheters placed by radiologists. *Radiology* 1996; 198: 467–472
13. Astor BC, Eustace JA, Powe NR *et al*. Timing of nephrologist referral and arteriovenous access use: the choice study. *Am J Kidney Dis* 2001; 38: 494–501
14. Weijmer MC, ter Wee PM. Temporary vascular access for hemodialysis treatment. Current guidelines and future directions. *Contrib Nephrol* 2004; 142: 94–111
15. Sesso R, Barbosa D, Leme IL *et al*. Staphylococcus aureus prophylaxis in hemodialysis patients using central venous catheter: effect of mupirocin ointment. *J Am Soc Nephrol* 1998; 9: 1085–1092
16. Vanherweghem JL, Dhaene M, Goldman M *et al*. Infections associated with subclavian dialysis catheters: the key role of nurse training. *Nephron* 1986; 42: 116–119

Received for publication: 5.11.06
Accepted in revised form: 1.10.07