

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

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## 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.

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## 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.<sup>1</sup> 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.<sup>2</sup> The use of CVCs among prevalent haemodialysis patients was 32% in 2009.<sup>2</sup>

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.<sup>3,4</sup> Furthermore, a CVC with catheter malfunction has to be removed eventually in most cases.<sup>5-7</sup> 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.<sup>3</sup> 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.<sup>6,8</sup> 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).<sup>9-12</sup> 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 <sup>2</sup> )	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.<sup>13–15</sup> 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  $p \leq 0.05$  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  $62 \pm 16$  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 (n=391)	Precurved jugular (n=635)	Straight jugular (n=210)	Straight femoral (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.<sup>16</sup> 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.<sup>6,8</sup> 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.<sup>17</sup> 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.<sup>13</sup> 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.<sup>18</sup> 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.<sup>5,8,17</sup> 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.

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