Diagnostic and Interventional Imaging (2019) **100**, 157—162

ORIGINAL ARTICLE /*Interventional imaging*

Patency rates of dysfunctional central hemodialysis venous catheter: Comparison between catheter exchange alone and catheter exchange with fibrin sheath angioplasty

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KEYWORDS
Catheter exchange;
Central venous catheter;
Fibrin sheath angioplasty;
Hemodialysis;
Patency rate

Abstract
Purpose: The purpose of this study was to compare patency rates and risk of obstruction of catheter exchange (CE) with that of CE with fibrin sheath angioplasty (CE + FSA) in dysfunctional tunneled central hemodialysis venous catheter (CHVC).
Materials and methods: A total of 107 consecutive patients with dysfunctional CHVC were retrospectively included. There were 66 men and 41 women with a mean age of 67.8 ± 12.5 (SD) years (range: 23.0—86.0 years). Seventy-three of 107 patients (68.2%) underwent CE procedure and 34 of 107 (31.8%) underwent CE + FSA. Kaplan—Meier log-rank test and multivariate Cox regression analyses were performed to determine patency rates and risk of obstruction according to type of endovascular procedure.

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https://doi.org/10.1016/j.diii.2018.08.013

Results: Patency rates after endovascular procedures at 3, 6, 12, 24 and 36 months follow up were 75%, 75%, 65%, 65% and 65% in CE + FSA group and 70%, 65%, 62%, 30% and 0% in CE group. Mean time until obstruction of CHVC was 778.4 days after CE + FSA and 497 days after CE ($P = 0.211$). Endovascular procedure was unrelated to risk of obstruction in adjusted model (HR = 1.34; $P = 0.515$).
Conclusions: Our findings suggest that both techniques are equivalent in terms of patency and safety results, so other aspects as cost assessment should be considered when choosing between both techniques.

Introduction

The submitted paper Central hemodialysis venous catheter (CHVC) represents the single vascular access option for hemodialysis for some patients [1,2] while arteriovenous fistula and graft are other options for hemodialysis access [3]. Despite of international recommendations, the use of CHVC still remains predominant [4]. According to the United States Renal Data System, 80% of patients initially had hemodialysis with a catheter, and nearly 70% for more than 90 days [5].

Complications due to catheter usage are associated with a non-negligible morbidity as well as extra costs [4,6]. Catheter dysfunction is a common complication [2] that is often due to the development of fibrin sheaths [6]. Fibrin sheath may lead to an alteration of catheter blood flow and it is also associated with other complications such as thrombosis and infection [6].

There are several treatment options in the management of fibrin sheath, including catheter exchange (CE) and fibrin sheath angioplasty with catheter exchange (CE + FSA). In 2006 KDOQI guidelines recommended CE + FSA in the absence of comparisons between different techniques in the literature [1]. Since then, few studies have been conducted to evaluate this issue. A recent systematic review [7] suggests that CE + FSA may be superior to CE alone in improving long-term CHVC survival although previous works did not demonstrated significant differences [8,9]. Therefore, there is insufficient evidence and further research is needed to address the question of which technique could be more effective for hemodialysis catheter dysfunction [7].

The purpose of this study was to compare patency rates and risk of obstruction of CE with that of CE + FSA in dysfunctional tunneled CHVC.

Materials and methods

Study design and patient selection

The database of the vascular radiology unit was queried to identify all patients with end-stage renal disease who underwent endovascular treatment of their dysfunctional CHVC from August 2005 to December 2016. The patients were considered eligible for inclusion when they had a first endovascular treatment of the central venous access due to CHVC dysfunction. Data were recorded during the procedure and included general characteristics of the patients, CHVC characteristics and endovascular treatment information. Written informed consent was obtained from all patients.

A total of 107 patients who underwent a total of 107 procedures were included. There were 66 men and 41 women with a mean age of 67.8 ± 12.5 (SD) years (range: 23.0—86.0 years). Seventy-three of 107 patients (68.2%) underwent CE procedure and 34 of 107 (31.8%) underwent CE + FSA.

CHVC dysfunction diagnosis

Patients were referred by a nephrologist due to CHVC dysfunction. The diagnostic of dysfunctional catheter was established by two expert interventional radiologists and established accordingly to failure to attain or maintain an extracorporeal blood flow > 300 mL/min at a prepump arterial pressure more negative than −250 mmHg or failure to maintain an extracorporeal blood flow sufficient to perform adequate hemodialysis without significantly lengthening the hemodialysis treatment [1].

Endovascular treatments

Patients diagnosed with CHVC dysfunction underwent either CE or CE + FSA. Both options were performed by two expert interventional radiologists accordingly to the VRU guidelines that were based on international standards and guidelines [1,2,10,11].

CE was performed over a guide wire. Under local anesthesia the catheters were dissected from the tunnel and retracted and a new catheter was then inserted over a 0.035-inch guide wire and advanced under fluoroscopic guidance through the previous subcutaneous tract. The tip of the new catheter was placed in the right atrium. When CE + FSA was chosen, iodinated contrast media was injected and the previous catheter was retracted over a guide wire under fluoroscopic guidance. Then angioplasty was performed with an 8—16-mm-wide, 4-cm-long angioplasty balloon (Bard). The balloon was then removed over a guide wire, and a new catheter was inserted and catheter tip was placed in

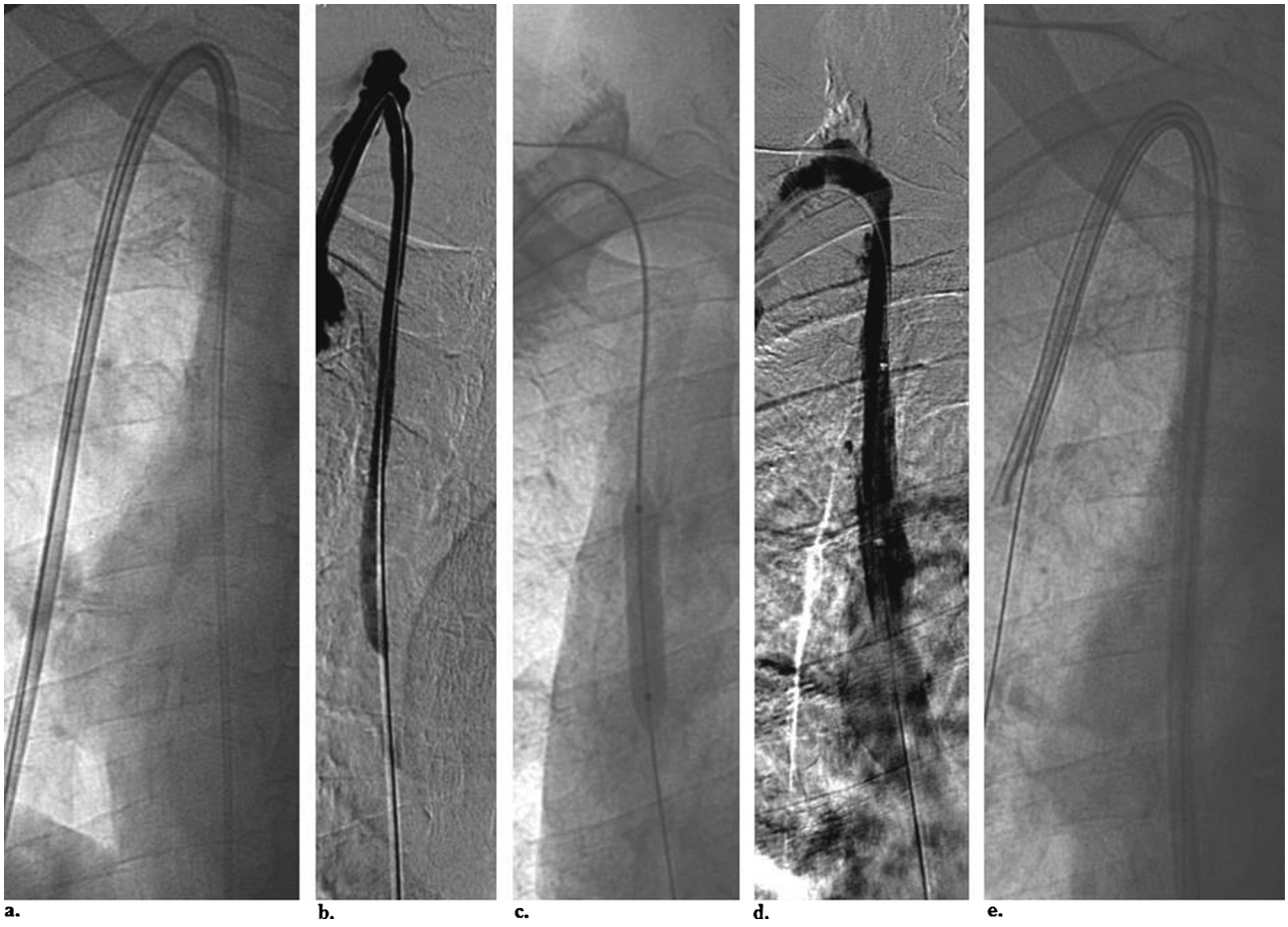

Figure 1. Catheter exchange and fibrin sheath angioplasty technique in a 62-year-old man with dysfunctional central hemodialysis venous catheter. A. The venous catheter is removed over a guide wire. B. Venogram shows fibrin sheath. C. The balloon catheter is inflated for angioplasty. D. Angiogram shows post-fibrin sheath angioplasty. E. A new catheter is placed.

the right atrium. Finally, a tractogram was performed after angioplasty to evaluate the degree of response (Fig. 1).

Follow-up and patency endpoint

Post-intervention patency follow-up including catheter complications were retrospectively reviewed using electronic medical records, including phlebography reports, by a medical research assistant. Phlebography of central veins was indicated where there was a suspicion of peri-catheter complications during the follow-up. Complications were categorized as catheter-related bloodstream infection, catheter-related thrombosis, edema, stenosis and mechanical complications. Catheter-related bloodstream infection consisted in bloodstream infection attributed to an intravascular catheter by positive culture of the catheter tip or by differences in growth between catheter and peripheral venipuncture blood culture specimens. Catheter-related thrombosis was diagnosed in the presence of difficulty with infusion or aspiration. Edema was diagnosed in the presence of superior vena cava syndrome. Mechanical complications included failure to place the catheter, arterial puncture, improper position, pneumothorax, hematoma, hemothorax, and asystolic cardiac arrest of unknown etiology.

Primary patency rate of CHVC after radiologic treatment was established on the basis of the SIR reporting standards and quality improvement guidelines [10,11] as the interval CHVC insertion until dysfunction with intervention in the CHVC.

Statistical analysis

Quantitative variables were expressed as mean ± standard deviation (SD) and range or median, interquartile range (25th—75th percentiles) and range for variables with non-parametric distributions. Qualitative variables were expressed s raw numbers, proportions and percentages (%). Normality of quantitative variables was evaluated with Kolmogorov—Smirnov test. Bivariate analysis using Chi^2 test, Yates' corrected Chi^2 test and Likelihood ratio test (for categorical variables), Student's *t*-test and Mann—Whitney U test (for continuous variables) were performed to search for differences between CHVC characteristics and procedures.

Kaplan—Meier method was performed to evaluate primary and secondary patency rates and standard error (SE) at 3, 6, 12, 24 and 36 months, and the mean survival and 95% confidence interval (CI). Log-rank test was used to compare patency rate differences between CE and CE + FSA.

Censored data occurred because of lost to follow up, study end and withdraw due to death, switch to peritoneal dialysis, renal transplantation, arteriovenous fistula or graft. Multivariate Cox proportional hazard regression analysis was used to determine potential risk of obstruction and patency loss between both endovascular procedures by adjusted hazard ratio (HR), with 95% CI. Endovascular procedure (catheter exchange —CE—, fibrin sheath angioplasty and catheter exchange —CE + FSA) and variables with *P*-value < 0.1 in bivariate analyses were introduced and analyzed by enter method to obtain a final adjusted model. Complications of CHVC during follow-up were analyzed using the Chi^2 test or the Yates' corrected Chi^2 test when appropriate to detect differences accordingly to both treatment options.

All tests were two tailed and the statistical significance level was set at ≤ 0.05. Analyses were performed with the IBM SPSS v.21 software (IBM Corporation, Armonk, NY, USA).

Results

No differences in age, gender distribution, and comorbidities were found between patients who underwent CE + FSA and those who underwent CE only (Table 1). The median age of CHVC until catheter replacement was 506.5 days in patients who underwent CE + FSA and 110 days in those who underwent CE only ($P < 0.001$). The main location of CHVC was the right internal jugular vein (21 of 34, 61.8% in CE + FSA group; 52 of 73, 71.2% in CE group) followed by left vein in both groups (10 of 34, 29.4% in CE + FSA group; 15 of 73, 20.5% in CE group) ($P = 0.397$). A minority of patients had had previous CHVC (5.9% in the CE + FSA group and 6.8% in the CE group; $P = 1.000$). No other associations were observed between treatment option and baseline characteristics (Table 1).

Post-intervention patency rates of CHVC at 3, 6, 12, 24 and 36 months are reported in Table 2. The mean patency duration was 778.4 days (95%CI: 604.8—951.9) in the CE + FSA group and 497.2 days (95%CI: 401.7—592.7) in the CE group. No significant differences were observed between both treatments (Kaplan—Meier log-rank test; $P = 0.211$). Endovascular procedure was unrelated to risk of obstruction in an adjusted model (HR = 1.34; 95% CI = 0.56—3.21; $P = 0.515$) (Fig. 2).

Complications during the follow-up according to the type of endovascular procedure are reported in Table 3. No significant differences in the total number of complications were found between patients who underwent CE + FSA (27.3%) and those who underwent CE alone (37.3%). Stenosis was the most frequent complication after CE + FSA (6/33; 18.2%) and thrombosis the most frequent one in the CE group (14/67; 20.9%). There were an increased number of thrombosis after CE in comparison to CE + FSA procedure ($P = 0.040$). However, the stratification sensitivity analysis using different cut-offs on CHVC age (60, 90, 100 days) did not show statistically significant differences among both procedures and complications ($P > 0.05$).

Table 1 Baseline characteristics of dysfunctional central hemodialysis venous catheter ($n = 107$).

Characteristic	CE + FSA ($n = 34$)	CE ($n = 73$)	*P*
Patient age (years)	69.4 ± 13.6 [38.0—86.0]	70.0 ± 11.9 [23.0-86.0]	0.357[a]
Female, (%)	14/34 (41.2)	27/73 (37.0)	0.678
Diabetes mellitus, (%)	18/34 (52.9)	34/73 (46.6)	0.540
Arterial hypertension, (%)	28/34 (82.4)	60/73 (82.2)	0.984
Dyslipidemia, (%)	16/34 (47.1)	33/73 (46.5)	0.956
Heart disease, (%)	15/34 (44.1)	36/73 (49.3)	0.616
Smoking, (%)	9/34 (26.5)	28/72 (38.9)	0.211
CHVC age, (days)	506.5 (325.5; 1026.5) [55.0—2279.0]	110.0 (48.5; 263.5) [3.0—1505.0]	< 0.001[b]
Location, *n*/N (%)			0.397[c]
Right internal jugular vein	21/34 (61.8)	52/73 (71.2)	
Left internal jugular vein	10/34 (29.4)	15/73 (20.5)	
Right femoral vein	3/34 (8.8)	4/73 (5.5)	
Left femoral vein	—	2/73 (2.7)	
Previous CHVC, *n*/N (%)	2/34 (5.9)	5/73 (6.8)	1.000[d]
CHVC length, *n*/N (%)			0.054[c]
32 cm	31/34 (91.2)	62/73 (84.9)	
40 cm	0/34 (0.0)	7/73 (9.6)	
55 cm	3/34 (8.8)	4/73 (5.5)	

CE: catheter exchange; CE + FSA: fibrin sheath angioplasty and CE; CHVC: central hemodialysis venous catheter. Patient age is expressed as mean ± standard deviation. Numbers in brackets are ranges. CHVC age is shown as median percentiles 25th, 75th in parenthesis and range in brackets.

[a] Student's *t*-test.

[b] Mann—Whitney U test.

[c] Likelihood ratio test. χ^2 test for the rest of variables

[d] Yates' corrected Chi^2 test.

Table 2 Post-intervention patency rates and mean duration of central hemodialysis venous catheter according to the type of endovascular procedure.

	CE + FSA		CE	
	Rate	SE	Rate	SE
3 months	75	(8)	70	(6)
6 months	75	(8)	65	(7)
12 months	65	(9)	62	(7)
24 months	65	(9)	30	(11)
36 months	65	(9)	0	(0)
	M	95% CI	M	95% CI
	778.4	604.8—951.9	497.2	(401.7—592.7)

CHVC: central hemodialysis venous catheter; CE: catheter exchange; CE + FSA: fibrin sheath angioplasty and CE. Rate: estimated percentage patent (%); SE: standard error (%). M: mean survival (days); CI: Confidence interval (days).

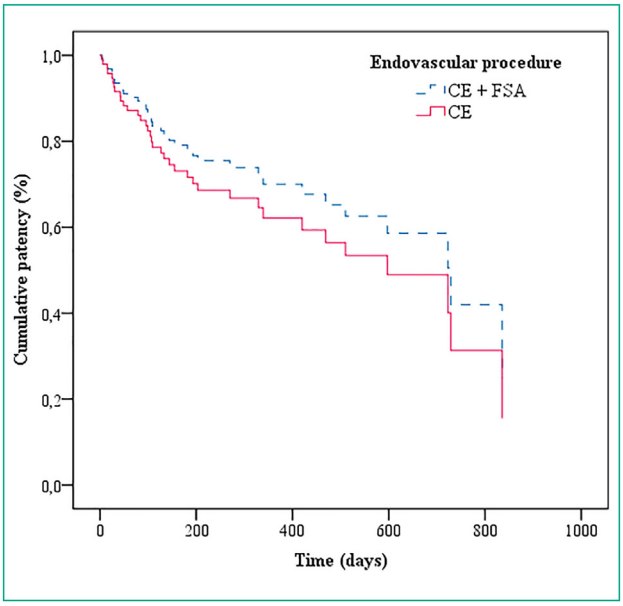

Figure 2. Graph shows post-interventional patency rates of dysfunctional central hemodialysis venous catheters according to the type of endovascular procedure in multivariate Cox regression model ($P = 0.515$). CE: Catheter exchange. CE + FSA: Fibrin sheath angioplasty and CE.

Discussion

In this retrospective study in dysfunctional tunneled CHVC for hemodialysis we found no differences in patency loss between CE alone and CE + FSA. No differences were found in relation to complications during the follow-up between both procedures.

Our findings tend to be more consistent with few studies that compared these endovascular procedures. Janne d'Othée et al. compared several treatment options in malfunctioning CHVC for hemodialysis [8]. In this retrospective study with a sample size of 33 and 15 hemodialysis catheters in CE and CE + FSA groups respectively, authors reported similar results in patency rates among both procedures. Besides, in this research they compared an additional technique, fibrin sheath stripping, with similar outcomes. In the absence of a clear benefit in these three techniques in terms of patency outcomes, authors concluded that other factors should be considered. A randomized clinical trial conducted by Oliver et al. that included 12 and 18 patients in CE and CE + FSA groups respectively, did not reach statistical significance between groups ($P = 0.17$) [9]. When compared to our study, cumulative patency rates were lower (at 6 months, 28% in CE and 39% in CE + FSA) [8] as well as patency days (78 and 198 days in CE [8,9], and 50 and 411 days in CE + FSA [8,9]). These different results may be due to a smaller sample size, the lack of adjustment for potential confounders, and differences in follow-up period, baseline characteristics and case selection, as the same central venous access could be included in more than one treatment group.

In relation to complications during follow-up, no significant differences were observed among both therapy groups. On the contrary, Ni et al. demonstrated using a bivariate analysis a decreasing association between CE + FSA group and developing of central venous stenosis (CVS) as well as the number of subsequent catheters used versus CE group [12]. In addition, another published work concluded that CE + FSA may reduce the risk of CVS when fibrin sheath is present in their catheter although there is a lack of a comparison group [13]. Quality Improvement Guidelines established a suggested threshold for thrombosis in 8% in jugular approaches while we observed 20.9% in CE group [14]. This threshold is based in limited literature and highly depended on patient selection. Our CE group included femoral insertion, and younger catheters may have higher rates of complications, including thrombosis [15].

Several limitations should be discussed. First, our population was small, although is the largest study done to date and represents the clinical practice in our VRU. A second limitation is related to the presumptive diagnosis of fibrin sheath in our dysfunctional catheters. It is possible that patients in the CE alone group had dysfunctional catheters for reasons other than a fibrin sheath. However, it has been reported that 70% of these malfunctioning CHVC developed a fibrin sheath [6]. Hence, in the majority of our cases fibrin sheath is present, or is likely to be present. Third, which criteria to apply in choosing one technique over another was not clearly established. Younger catheters were more prone to

Table 3 Development of complications in central hemodialysis venous catheter after endovascular procedure during follow-up.

Complications	CE + FSA	CE	*P*[a]	
	n/N (%)	*n*/N (%)	Total	Stratified[b]
Infection	0/33 (0)	1/67 (1.5)	NS	NS
Thrombosis	1/33 (3.0)	14/67 (20.9)	0.040	NS
Edema	1/33 (3.0)	1/67 (1.5)	NS	NS
Stenosis	6/33 (18.2)	7/67 (10.4)	NS	NS
Mechanical complications	1/33 (3.0)	2/67 (3.0)	NS	NS
Total	9/33 (27.3)	25/67 (37.3)	NS	NS

CE: catheter exchange; CE + FSA: fibrin sheath angioplasty and CE. Number of cases with missing data: 1 for CE + FSA group, 6 for CE group. NS: Not significant.
[a] χ^2 test for total complications, Yates' corrected Chi^2 test for the rest of variables.
[b] Sensitivity analysis using 3 different cut-offs of CHVC age (60, 90, 100 days).

receive CE treatment, so the lack of randomization may led this characteristic influence in our results. In contrast, we took into account in the analyses possible confounding factors such as CHVC age. Definitely, prospective randomized studies to confirm our findings are warranted.

In conclusion, our results suggest that CE and CE + FSA have equivalent patency and safety results in malfunctioning tunneled CHVC for hemodialysis. Our findings, if confirmed by future research, may suggest that a cost assessment, among other aspects, should be considered when choosing between both techniques.

Disclosure of interest

The authors declare that they have no competing interest.

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