



Reversed connection of cuffed, tunneled, dual-lumen catheters with increased blood flow rate maintains the adequacy of delivered dialysis despite the higher access recirculation

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Received: 1 July 2019 / Accepted: 26 August 2019 / Published online: 30 August 2019
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Abstract

Purpose Reversing the connection mode of permanent dual-lumen dialysis catheters results in higher access recirculation that may compromise the dialysis adequacy. The purpose of this study is to investigate the effect of reversed-connected dialysis with a higher versus a standard blood flow rate (Q_b) on adequacy parameters and access recirculation.

Materials and methods In a cross-over design, 46 prevalent dialysis patients with a properly functioning cuffed, tunneled, dual-lumen catheter were evaluated in three consecutive mid-week dialysis sessions. At baseline, participants were evaluated under standardized conditions (correct connection, $Q_b = 300$ ml/min). In Phase A, dialysis was performed with reversed connection and $Q_b = 300$ ml/min. In Phase B, dialysis was performed with reversed connection and $Q_b = 400$ ml/min. The sequence of evaluations (Phase A and B or vice versa) was randomized. All other dialysis-related parameters were unchanged in all three occasions.

Results As expected, compared with baseline, reversed-connected dialysis in Phase A resulted in lower URR and $spKt/V$, and in a higher recirculation rate. Compared with baseline, reversed-connected dialysis with a higher Q_b in Phase B resulted in an even higher recirculation rate, but the parameters of dialysis adequacy were not different. Increase in Q_b from 300 to 400 ml/min resulted in an improvement of the dialysis adequacy (URR: $64.1 \pm 7.8\%$ vs. $70.6 \pm 8.2\%$, $P < 0.001$; $spKt/V$: 1.22 ± 0.3 vs. 1.45 ± 0.3 , $P < 0.001$) despite the higher recirculation rate.

Conclusion This study suggests that reversed-connected dialysis with increasing Q_b maintains the adequacy of the delivered dialysis despite the compensatory increase in recirculation.

Keywords Adequacy · Central venous catheter · Dialysis · Recirculation

Introduction

Although the National Kidney Foundation-Dialysis Outcomes Quality Initiative (NKF-DOQI) guidelines recommend the initiation and maintenance of long-term hemodialysis either with an arteriovenous fistula or with an arteriovenous graft [1], a large proportion of end-stage-renal-disease (ESRD) patients worldwide—ranging from 1 to 45% across 20 countries in 2013—continue to use central venous catheters (CVCs) as permanent vascular access [2, 3]. Apart from the higher incidence of infection-related adverse events [4, 5], CVC use is also associated with hazards arising from the inability to achieve the recommended by guidelines dialysis adequacy targets owing to catheter dysfunction. This clinical complication is attributable to a variety of reasons, including thrombus formation, fibrin

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sheath, central vein stenosis, or malposition [6]. A therapeutic approach commonly applied in daily clinical practice to overcome the barrier of catheter dysfunction, attain sufficient blood flow rates and provide adequate dialysis without the necessity for lengthening the duration of renal replacement therapy is to reverse the connection mode of dysfunctioning dual-lumen CVCs [6].

Earlier studies have raised substantial uncertainty on the efficacy of this therapeutic maneuver, showing that dialysis with reversed-connected lines is associated with higher rates of access recirculation that compromise the adequacy of the delivered dialysis [7–12]. The reported access recirculation was <5% with correct connection, but increased up to 13% with reversed connection [7–12]. Studies using the ultrasound dilution technique have reported even higher rates of access recirculation, ranging up to 18% or 24% with reversed-connected dual-lumen CVCs [13]. This heterogeneity may be also explained by a number of inherent methodological limitations of these studies, including small sample sizes, non-randomized order of patient evaluation, and enrollment of patients either with dysfunctioning or with properly functioning CVCs. More recent studies have shown that the increase in access recirculation and decrease in dialysis adequacy parameters with reversed-connected lines depend on the degree of elevation in blood flow rate [14, 15]. It has to be noted, however, that these studies were based on mathematical modeling of urea kinetics instead of real-time measurements of the clearance and recirculation of urea [14, 15].

Accordingly, the aim of this study is to evaluate the impact of reversed-connected dialysis with a higher ($Q_b = 400$ ml/min) versus a standard ($Q_b = 300$ ml/min) blood flow rate on parameters of adequacy and on access recirculation, using correct connection mode with a regular blood flow ($Q_b = 300$ ml/min) as reference standard.

Materials and methods

Study population

A total of 46 adult ESRD patients receiving maintenance hemodialysis therapy in Therapeutiki Dialysis Unit, Thessaloniki, Greece, participated in this study. Patients were eligible for this study in case of using a properly functioning cuffed, tunneled, dual-lumen CVC as permanent vascular access for dialysis for at least 3 months prior to study enrollment. Exclusion criteria of the study consisted of (i) current use of temporal or single-lumen CVCs; (ii) CVC dysfunction, defined as failure to attain and maintain a blood flow rate of ≥ 300 ml/min that is sufficient to provide adequate dialysis without significant lengthening of the session duration [1]; (iii) active CVC-related bloodstream infection; (iv)

regular symptomatic episodes of intradialytic hemodynamic instability requiring intravenous saline infusion; (v) acute myocardial infarction, unstable angina or acute stroke during 1 month prior to study enrollment; (vi) active malignancy or any other non-cardiac co-morbidity associated with poor short-term prognosis.

All study investigators declare their adherence to the Declaration of Helsinki (2013 Amendment). The study protocol was approved by the Ethics Committee of School of Medicine, Democritus University of Thrace, and all participants provided informed written consent prior to study enrollment.

Study design

This study followed a randomized, cross-over design. In detail, study participants underwent a baseline evaluation with correct connection mode of CVCs and standard blood flow rate ($Q_b = 300$ ml/min) during a mid-week dialysis session (Week 0: Wednesday or Thursday). Subsequently, study participants were evaluated in two different study phases during the mid-week dialysis sessions of Week 1 and Week 2 (1 week apart). In Phase A, the mid-week dialysis session was performed with reversed-connected lines and standard blood flow rate ($Q_b = 300$ ml/min). In Phase B, the mid-week dialysis session was performed with reversed-connected lines and a higher blood flow rate ($Q_b = 400$ ml/min). The sequence of evaluations (Phase A and Phase B or vice versa) was randomized. All other dialysis-related parameters (i.e., dialysate flow rate, type of dialyzer, session duration, CVC lock, etc) remained unchanged in all three occasions. Throughout the study period, participants underwent their regular dialysis treatments, during which ultrafiltration volume was programmed according to their prespecified dry weight that was defined on the basis of standard clinical criteria. No modifications in dry weight were permitted during the study.

Protocol procedures

At baseline evaluation, study investigators collected information with respect to the demographic and anthropometric characteristics of study participants, primary cause of ESRD, co-morbidities and dialysis-related parameters using a purpose-built data-collection sheet. Assessment of dialysis adequacy was performed by calculating the urea reduction ratio (URR) and the K_t/V . Blood samples were acquired at the start and end of each dialysis session for the determination of plasma urea concentrations, according to the guideline recommendations and using the slow flow method [16]. The URR was calculated using the equation: $(\text{pre-dialysis urea} - \text{post-dialysis urea}) / \text{pre-dialysis urea}$ [16]. The K_t/V was calculated using the Daugirdas formula: $K_t/V = -\ln(R - 0.03) + [(4 - 3.5R) \times (UF/W)]$, where UF is the

ultrafiltration volume in liters, W is the post-dialysis weight in kg and R is the ratio of the post-dialysis-to-pre-dialysis urea [17]. Participants with residual renal function were eligible in this study, but the renal clearance of urea was not inserted in the Kt/V estimation. Suboptimal dialysis adequacy was defined as single-pool Kt/V (sp Kt/V) < 1.2 or URR < 65% [16].

Access recirculation was estimated using the slow flow method (18). In detail, 30 min after dialysis initiation, ultrafiltration was stopped and three blood samples were obtained for the determination of plasma urea concentrations. The first sample was obtained from the inflow line (arterial, a), the second from the outflow line (venous, v) and the third from the inflow line after setting the blood flow rate to 100 ml/min for 30 s (peripheral, p). Access recirculation was calculated using the formula: $[(p - a)/(p - v)] \times 100$ (18). Excess recirculation was defined as a recirculation rate > 10% [18].

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences 23 (SPSS Inc, Chicago, Illinois, USA). Continuous variables are expressed as mean values \pm standard deviation (SD) or median and range. Categorical variables are presented as frequencies and percentages (n , %). The normality of distribution of each variable was assessed using the Kolmogorov–Smirnov or the Shapiro–Wilk test. Comparisons for continuous variables were performed with the paired Student's t test or with the Wilcoxon's signed rank test, according to the normality of the distribution. Comparisons for categorical variables were performed with the Chi-squared (χ^2) test. To explore the association between dialysis adequacy parameters and the rate of access recirculation, we performed bi-variate correlation analysis using the Spearman co-efficient. Probability values of $P < 0.05$ (two tailed) were considered statistically significant for all comparisons.

Results

The baseline demographic and clinical characteristics of study participants are depicted in Table 1. A total of 46 prevalent hemodialysis patients (19 men and 27 women) with a mean age of 78.8 ± 7.6 years and a median dialysis vintage of 11.5 (range 64.0) months were enrolled in this study. The most frequent primary cause of ESRD was diabetic nephropathy, whereas approximately one-third of study participants had a history of coronary artery disease (32.6%) or a history of congestive heart failure (34.8%). With respect to the distribution of CVC location, 29 participants (63.0%) had a permanent vascular access in the right internal jugular

Table 1 Baseline characteristics of study participants

Parameter	Value
N	46
Age (years)	78.8 ± 7.6
Gender (n , %)	
Male	19 (41.3)
Female	27 (58.7)
Dialysis vintage (months)	11.5 (64.0)
Post-dialysis weight (kg)	73.5 ± 15.4
Dialysis session duration (min)	213.6 ± 19.0
Primary cause of ESRD (n , %)	
Diabetes	26 (56.5)
Hypertension	2 (4.3)
Glomerulonephritis	2 (4.3)
Obstructive uropathy	2 (4.3)
Chronic cardio-renal syndrome	2 (4.3)
Unknown	12 (26.1)
Co-morbidities (n , %)	
CHD	15 (32.6)
CHF	16 (34.8)
Stroke	8 (17.4)
Laboratory parameters	
Hemoglobin (g/dl)	11.4 ± 0.9
Serum urea (mg/dl)	124.6 ± 35.7
Serum creatinine (mg/dl)	6.2 ± 1.8
Serum potassium (mmol/l)	4.9 ± 0.8
Serum sodium (mmol/l)	139.2 ± 3.3
Serum calcium (mg/dl)	8.8 ± 0.6
Serum phosphate (mg/dl)	4.5 ± 0.9
Serum albumin (g/dl)	3.9 ± 0.4
PTH (pg/dl)	197.4 ± 31.6
Duration of CVC use (months)	6.5 (37)
Distribution of CVC sites (n , %)	
Right internal jugular vein	29 (63.0)
Left internal jugular vein	1 (2.2)
Right subclavian vein	16 (34.8)
CVC tip (n , %)	
Staggered	45 (97.8)
Split	1 (2.2)
Tip-to-cuff length (n , %)	
19 cm	13 (28.3)
23 cm	33 (71.7)
Tip location in right atrium (n , %)	46 (100)
CVC lock (n , %)	
Heparin	36 (78.3)
TauroLock-Hep500	10 (21.7)

CVC central venous catheter, CAD coronary artery disease, CHF congestive heart failure, ESRD end-stage renal disease, PTH parathyroid hormone

Data are presented as mean \pm SD or median (range), according to the normality of distribution

vein, 16 participants (34.8%) in the right subclavian vein and 1 participant (2.2%) in the left internal jugular vein. With the exception of one participant with a split tip CVC, all other study participants (97.8%) had a staggered tip.

Dialysis adequacy parameters and access recirculation rates at baseline evaluation and in Phase A and B of the study are presented in Table 2. Median pressure in the arterial and venous lines as well as median transmembrane pressure did not differ between the baseline evaluation and Phase A. As expected, the higher blood flow rate in Phase B resulted in higher median pressures in the arterial and venous lines. Compared with the baseline evaluation, dialysis with reversed-connected lines and standard blood flow rate of 300 ml/min in Phase A resulted in lower URR ($68.9 \pm 9.2\%$ vs. $64.1 \pm 7.8\%$, $P < 0.001$) and in lower spKt/V (1.39 ± 0.4 vs. 1.22 ± 0.3 , $P = 0.001$) that was paralleled with a significantly higher recirculation rate of urea. By contrast, dialysis adequacy parameters did not significantly differ between the baseline evaluation and Phase B (URR: $68.9 \pm 9.2\%$ vs. $70.6 \pm 8.2\%$, $P = 0.23$; spKt/V: 1.39 ± 0.4 vs. 1.45 ± 0.3 , $P = 0.39$); this effect was evident despite the significantly higher rate in access recirculation with reversed-connected dialysis and a higher blood flow rate of 400 ml/min. Compared with the standard blood flow rate in Phase A, reversed-connected dialysis with a blood flow rate of 400 ml/min in Phase B improved the adequacy of the delivered dialysis (URR: $64.1 \pm 7.8\%$ vs. $70.6 \pm 8.2\%$, $P < 0.001$; spKt/V: 1.22 ± 0.3 vs. 1.45 ± 0.3 , $P < 0.001$), despite the significantly higher rate of access recirculation (Table 2).

As shown in Table 3, the effect of reverse-connected dialysis with a blood flow of 300 or 400 ml/min on parameters of dialysis adequacy as well as on the rate of recirculation of urea was unmodified regardless of the duration of CVC

use (i.e., ≥ 12 months vs. < 12 months). We also performed correlation analysis to explore the association of dialysis adequacy parameters with access recirculation. Neither the URR (Spearman co-efficient: 0.084, $P = 0.31$) nor the spKt/V (Spearman co-efficient: 0.094, $P = 0.28$) were significantly associated the rate of recirculation of urea.

As shown in Fig. 1, the proportion of participants with suboptimal dialysis adequacy determined in terms of a spKt/V < 1.2 was 26.1% at baseline evaluation, 45.7% in Phase A and 17.1% in Phase B ($P = 0.41$ for the linear-by-linear association across phases). By contrast, the proportion of participants with excess recirculation $> 10\%$ was 10.9% at baseline evaluation, 30.4% in Phase A and 56.8% in Phase B ($P < 0.001$ for the linear-by-linear association across phases).

Discussion

The aim of this study was to evaluate the effect of reserved-connected dialysis with a higher ($Q_b = 400$ ml/min) versus a standard ($Q_b = 300$ ml/min) blood flow rate on the adequacy of the delivered dialysis and access recirculation in hemodialysis patients with a properly functioning cuffed, tunneled, dual-lumen CVC as permanent vascular access. The main findings of this study are the following: (i) using the same standard blood flow rate of 300 ml/min, reversed connection mode lowered the adequacy of the delivered dialysis and increased the rate of access recirculation in comparison with the correct connection mode; (ii) using a higher blood flow rate of 400 ml/min with reversed connection mode resulted in even higher rates of access recirculation, but improved the dialysis adequacy parameters; (iii) although 56.8% of participants in Phase B had excess recirculation

Table 2 Dialysis adequacy and recirculation rate of urea with reversed-connected lines and increasing blood flow rates

Parameter	Baseline (correct connection, Q_b : 300 ml/min)	Phase A (reversed connection, Q_b : 300 ml/min)	P^a value	Phase B (reversed connection, Q_b : 400 ml/min)	P^b value	P^c value
Median arterial pressure (mmHg)	116.0 \pm 29.0	118.7 \pm 18.5	0.49	168.3 \pm 23.9	< 0.001	< 0.001
Median venous pressure (mmHg)	114.0 \pm 19.0	115.1 \pm 19.1	0.69	142.7 \pm 24.3	< 0.001	< 0.001
Median transmembrane pressure (mmHg)	38.0 \pm 24.6	40.1 \pm 26.8	0.48	43.5 \pm 34.9	0.31	0.48
Pre-dialysis urea (mg/dl)	124.6 \pm 35.7	121.6 \pm 27.9	0.47	119.4 \pm 29.6	0.14	0.51
Post-dialysis urea (mg/dl)	36.9 \pm 13.5	42.5 \pm 13.2	0.004	35.0 \pm 13.5	0.30	< 0.001
Urea reduction ratio (%)	68.9 \pm 9.2	64.1 \pm 7.8	< 0.001	70.6 \pm 8.2	0.23	< 0.001
spKt/V	1.39 \pm 0.4	1.22 \pm 0.3	0.001	1.45 \pm 0.3	0.39	< 0.001
Recirculation rate of urea (%)	3.3 (13)	4.0 (24.8)	0.02	11.9 (45.3)	< 0.001	< 0.001

Data are presented as mean \pm SD for all variables with the exception of recirculation rate of urea that is presented as median (range)

P^a value: comparison between baseline and Phase A

P^b value: comparison between baseline and Phase B

P^c value: comparison between Phase A and Phase B

Table 3 Subgroup analysis stratified according to the duration of central venous catheter use

Parameter	Baseline (correct connection, Qb: 300 ml/min)	Phase A (reversed connection, Qb: 300 ml/min)	P^a value	Phase B (reversed connection, Qb: 400 ml/min)	P^b value	P^c value
Central venous catheter use \geq 12 months ($n=16$)						
Urea reduction ratio (%)	69.4 \pm 8.9	65.2 \pm 9.1	0.07	70.0 \pm 9.1	0.82	0.005
spKt/V	1.40 \pm 0.4	1.24 \pm 0.3	0.06	1.425 \pm 0.3	0.86	0.003
Recirculation rate of urea (%)	2.4 (13.0)	1.7 (16.0)	0.59	8.2 (45.3)	0.02	0.009
Central venous catheter use < 12 months ($n=30$)						
Urea reduction ratio (%)	68.7 \pm 9.4	63.5 \pm 7.2	0.002	70.9 \pm 7.9	0.19	< 0.001
spKt/V	1.38 \pm 0.4	1.20 \pm 0.3	0.009	1.46 \pm 0.3	0.37	< 0.001
Recirculation rate of urea (%)	3.6 (12.0)	6.9 (24.8)	0.005	12.7 (35.0)	< 0.001	0.005

Data are presented as mean \pm SD for all variables with the exception of recirculation rate of urea that is presented as median (range)

P^a value: comparison between baseline and Phase A

P^b value: comparison between baseline and Phase B

P^c value: comparison between Phase A and Phase B

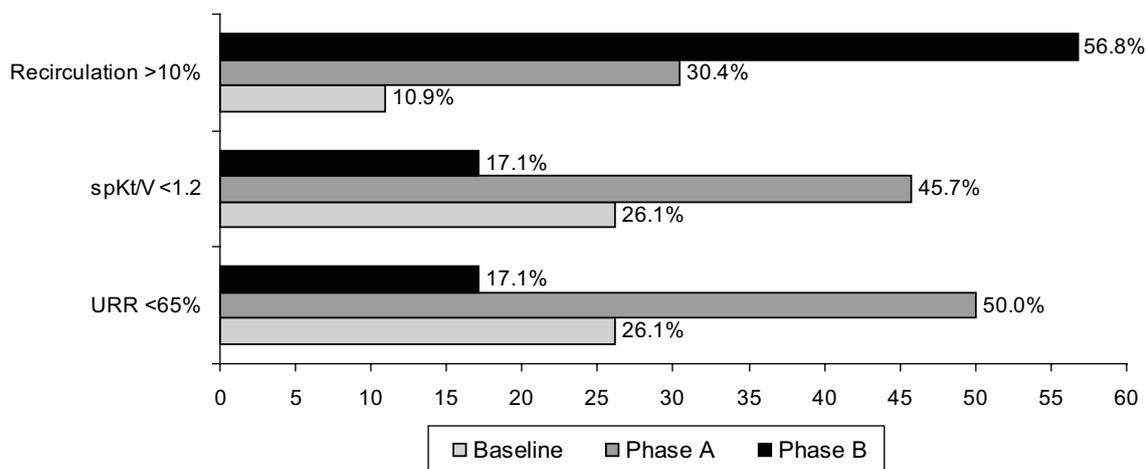


Fig. 1 Proportion of study participants with URR < 65%, spKt/V < 1.2 and recirculation rate of urea > 10% at baseline, Phase A and Phase B. Comparison across study phases: URR: $P=0.43$; spKt/V: $P=0.41$ recirculation rate: $P<0.001$

rate > 10%, only 17.1% of participants had a sub-optimal dialysis adequacy determined either with an URR < 65% or with a spKt/V < 1.2.

In accordance with the results of the present study, several earlier studies evaluating the dialytic efficacy according to the connection mode of dual-lumen CVCs have shown that dialysis with reversed-connected lines results in a significantly higher access recirculation [7, 9, 13]. For example, in a cross-over study of 12 hemodialysis patients, Sombolos et al. [12] showed that the rate of access recirculation was significantly higher with reversed-connected than with correct-connected lines (8.25 \pm 2.7% vs. 4.25 \pm 1.0%, $P<0.001$) (12). Reversing the connection mode of dysfunctioning dual-lumen CVCs continues to be widely applied in daily clinical practice as a “rescue”

therapeutic maneuver that enables the achievement of higher blood flow rates to provide adequate dialysis. This maneuver is beneficial to the extent at which the higher blood flow rates achieved with the reversed connection mode can counteract the compensatory increase in access recirculation. Using the ionic dialysance technique, Carson et al. (8) showed that reversing the connection mode of dysfunctional dual-lumen CVCs was associated with improvement in mean urea clearance from 128 \pm 10 ml/min at a blood flow rate of 200 ml/min to 157 \pm 38 ml/min at maximal blood flow rate ($P<0.05$). Reversed connection mode improved the adequacy of the delivered dialysis despite the parallel increase in access recirculation at a mean rate of 25 \pm 16% [8]. In correlation analysis, the achieved blood flow rates with reversed-connected lines

had no association with the increase in the rate of access recirculation ($r^2 = 0.10$) [8].

The present study expands the above observations, providing a direct comparison of the effect of reversed connection mode with a higher versus a standard blood flow rate. Increasing the blood flow rate from 300 to 400 ml/min was accompanied by an improvement in the adequacy of the delivered dialysis despite the compensatory increase in the recirculation rate. The vast majority of participants in Phase B achieved an URR > 65% or a spKt/V > 1.2 and these rates were comparable with the baseline evaluation that was conducted under standardized conditions. Studies using mathematical modeling of urea kinetics provide additional support to the notion that increasing blood flow rates in an “appropriate” extent may counteract the loss in urea clearance inducible by the higher access recirculation with reversed-connected dialysis [14, 15]. In a cross-over study of 22 hemodialysis patients, Van Biesen et al. [14] showed that the total solute removal (TSR) of urea did not significantly differ between correct-connected and reversed-connected dialysis (301 ± 112 vs. 293 ± 104 mmol, $P = 0.354$). In a kinetic model simulating the TSR of urea for different rates of access recirculation and varying blood flow levels, it was shown that for a recirculation of 5–25%, reversion of the connection mode requires a compensatory increase in blood flow rate by 6.7% and 52.0%, 8.5% and 72.0%, and 10.0% and 115.2%, for a blood flow rate in the correct connection mode of 150, 200 and 250 ml/min, respectively [14]. It has to be noted, however, that these modeled data require confirmation by dose-ranging studies testing different blood flow rates with reversed and correct connection mode of dual-lumen CVCs in real-time conditions. The present study provided data in this direction.

Despite the fact that the large sample size and the randomized, cross-over design are important strengths, the present study has also some limitations that need to be acknowledged. Study evaluations were restricted to the estimation of the clearance and recirculation rate of urea and did not include the reduction ratios for phosphorous, β_2 -microglobulin or other uremic toxins with a higher molecular weight. Although urea removal represents the standard-of-care in the assessment of dialysis adequacy, future studies evaluating the removal of β_2 -microglobulin or other uremic toxins are warranted to fully elucidate the dialytic efficacy of reversed versus correct connection mode of dual-lumen CVCs. In addition, the present study evaluated the effect of a higher versus a standard blood flow rate in a single mid-week dialysis session. Although the assigned blood flow rate of 400 ml/min in Phase B was achieved in the whole study population without complications, the feasibility of intensifying the blood pump flow in patients dialyzed with reversed connection mode due to catheter dysfunction remains uncertain. It

has to be noted that the present study was conducted in patients with properly functioning CVCs but the approach of reversed-connection mode is commonly used in case of dysfunctioning dialysis access. Although the results of our analysis are provocative, the feasibility and efficacy of reverse-connected dialysis with increasing blood flow rates needs to be explored in future studies enrolling participants with CVC dysfunction.

In conclusion, the present study shows that relative to reversed-connected dialysis with a standard blood flow rate ($Q_b = 300$ ml/min), increasing the blood flow rate to 400 ml/min improves the adequacy of the delivered dialysis despite the higher rate of access recirculation. These results have important clinical implications and provide some scientific basis to the reversion of the connection mode of dysfunctioning catheters as an initial, non-interventional, therapeutic approach to achieve the recommended by guidelines targets on dialysis adequacy.

Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to disclose.

Financial support This study was not supported by any source and represents an original effort of our part.

Ethical statement This article is the result of our independent research work. Except for the contents quoted in the article, this paper does not contain the results of any other people or collectively published works.

Informed consent This research involves human participants; they have signed the informed consent.

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