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Prevention of tunneled haemodialysis catheter-related dysfunction and bacteraemia using a closed-system connector with a neutral valve: a quasi-experimental before and after study

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ABSTRACT

Introduction: The use of tunneled central venous catheters in haemodialysis is frequently associated with catheter-related bacteraemia. The closed-system connector with a neutral valve emerges as an alternative to reduce this risk by limiting manipulation of the catheter lumen.

Objective and Hypothesis: To evaluate whether the systematic use of closed-system connectors with a neutral valve decreases the rate of catheter-related bacteraemia. It was hypothesised that its use would significantly reduce both complications.

Material and Method: We conducted a retrospective, quasi-experimental, before-after study in a regional hospital over 12 months. A total of 62 catheters in 55 patients were included. Rates of catheter-related bacteraemia per 1,000 catheter-days were evaluated, in addition to parameters on catheter function. Statistical tests for proportion comparison and Pearson's regression were applied.

Results: The rate of catheter-related bacteraemia was reduced from 1.25 to 0.15 per 1,000 catheter-days after the introduction of closed-system connectors with a neutral valve. A total of 100% of the catheters maintained desirable arterial and venous pressure values, 95.2% an adequate blood flow, and 40.3% achieved optimal dialysis dose, with lower performance in males.

Conclusions: The use of closed-system connectors with a neutral valve significantly decreased infections without affecting catheter function. Robust multicentre studies are needed to confirm effectiveness.

Keywords: central venous catheters; haemodialysis; catheter-related infections; needleless connectors/neutral valve; before and after controlled studies.

ABSTRACT

Prevención de la disfunción y bactiriemia relacionadas con el catéter de hemodiálisis tunelizado mediante un conector de sistema cerrado con válvula neutra: estudio cuasi-experimental antes-después

Introducción: El uso del catéter venoso central tunelizado en hemodiálisis se asocia frecuentemente con bacteriemia relacionada con el catéter. El conector de sistema cerrado con válvula neutra surge como alternativa para reducir este riesgo al limitar la manipulación del lumen del catéter.

Objetivos e Hipótesis: Evaluar si el uso sistemático de conectores de sistema cerrado con válvula neutra disminuye la incidencia de bacteriemias relacionadas con el catéter. Se planteó como hipótesis que su uso reduciría significativamente ambas complicaciones.

Material y Método: Estudio cuasi-experimental retrospectivo, tipo antes-después, en un hospital comarcal, durante 12 meses. Se incluyeron 62 catéteres en 55 pacientes. Se evaluaron tasas de bacteriemia relacionada con el catéter por 1.000 días-catéter, además de parámetros sobre función del catéter. Se aplicaron pruebas estadísticas de comparación de proporciones y regresión de Pearson.

Resultados: La tasa de bacteriemia relacionada con el catéter se redujo de 1,25 a 0,15 por 1.000 días-catéter tras la introducción de los conectores de sistema cerrado con válvula neutra. El 100% de los catéteres mantuvo valores deseables de presión arterial y venosa, el 95,2% un flujo de sangre adecuado y el 40,3% alcanzó dosis de diálisis óptima, con menor rendimiento en varones.

Conclusiones: El uso de conectores de sistema cerrado con válvula neutra disminuyó de forma significativa las infecciones sin afectar el funcionamiento del catéter. Se necesitan estudios multicéntricos robustos para confirmar efectividad.

Palabras clave: catéteres venosos centrales; hemodiálisis; infecciones relacionadas con catéteres; conectores sin aguja/con válvula neutra; estudios controlados antes y después.

Centers for Disease Control and Prevention (CDC) guideline cautions that the available evidence for its specific use in HD is still limited and does not permit its widespread recommendation, restricting its indication to selected cases. Despite this cautious recommendation, recent studies have provided data supporting the efficacy of these devices in reducing infectious events and catheter dysfunction. The randomised clinical trial by Bonkain et al[5] showed a significant reduction in both catheter dysfunction and associated bacteraemia with the use of CSCNV in a cohort of HD patients. In the same vein, research by Brunelli et al[6] and Guembe et al[7] have reported a reduction in colonisation and infection rates when using Tego™-type connectors. Similarly, interventional studies such as that by Weiss and Qureshi[8] and the cluster trial by Brunelli et al[9] reinforce the potential of these devices as part of prevention strategies in routine clinical practice. Furthermore, a more recent study in a paediatric HD population by Nau et al[10] has shown similar benefits with devices like ClearGuard™, suggesting broader applicability in vulnerable groups. In this context, it is clinically relevant to evaluate the impact of introducing CSCNVs in preventing infectious complications in HD units. This study aims to provide new evidence from real-world practice, complementing existing clinical trials and contributing to the justification of future clinical guideline updates.

The hypothesis of our study was that the implementation of CSCNV in HD TCVCs would significantly reduce the incidence of CRB and the rate of catheter dysfunction, compared to direct connection. The study's objective was to evaluate the impact of introducing the CSCNV in HD TCVCs on the incidence of CRB and the rate of catheter dysfunction.

INTRODUCTION

The use of tunneled central venous catheters (TCVCs) is an alternative to arteriovenous fistulas (AVFs) for renal replacement therapy in haemodialysis (HD). However, TCVCs are not without complications, with catheter-related bacteraemia (CRB) being one of the most significant. CRB represents a major cause of morbidity, mortality, hospitalisation, and increased healthcare costs in this patient population[1,2].

With the aim of reducing these infection rates, devices such as the closed-system connector with a neutral valve (CSCNV) have been developed. This sterile, disposable valve is indicated for use in chronic HD, haemofiltration, haemodiafiltration, and apheresis. This device acts as a mechanically and microbiologically closed system, connected to the TCVC lumens on the first session day of the week, replacing the traditional cap, and can remain in place for a maximum of 7 days[3,4]. Its design reduces the catheter lumen's exposure to the environment, minimising manipulation and, consequently, the risk of intraluminal contamination.

Clinical practice guidelines have proposed various strategies, including the use of CSCNVs. However, the updated 2017

MATERIAL Y METHOD

Study Design

We conducted a retrospective quasi-experimental "before-and-after" study with patients with TCVCs on HD treatment at a district hospital.

The 'before' period (direct connection) was conducted between March 2021 and March 2022. The 'after' period (CSCNV use) was conducted between April 2022 and April 2023.

This report has been drafted in accordance with the TREND (Transparent Reporting of Evaluations with Nonrandomised Designs) statement[11].

Participants

Adult patients on HD treatment via TCVCs, who had 3 weekly sessions during the study period, were included. Patients receiving antibiotic treatment during the evaluation period, patients with NTCVCs, and patients who refused to participate in the study were excluded.

Participant selection was nonrandomised. Recruitment was performed via consecutive sampling, including all patients who met the established inclusion criteria. Informed consent was obtained from patients to access their computerised clinical data.

Interventions Under Study
During the 'before' period (direct connection), TCVCs were connected directly to the HD circuit lines, using sterile caps after sealing for inter-dialysis periods. Each manipulation required thorough cleaning of the connection point with alcoholic chlorhexidine. There was no additional barrier mechanism between the catheter and the infusion system, which could increase the risk of contamination during manipulation.

During the 'after' period (CSCNV use), DiaSeal® neutral valves from B. Braun[4] were employed. This is a needle-free, Luer-activated connector designed for central venous catheters (CVCs) in extracorporeal therapies. It features an internal silicone mechanism that keeps the catheter closed between sessions, automatically opening when a male Luer cone is connected, allowing for direct and adequate flow for treatments such as HD. Its closed design eliminates the need for additional caps, permitting continuous use for up to 7 days[4]. This CSCNV has an internal priming volume of 0.09 mL and allows for blood sample collection. Its smooth surface facilitates disinfection, contributing to reducing the risk of catheter-related infections[4]. These devices were replaced every 7 days or sooner if signs of deterioration were present, according to the manufacturer's recommendations[4]. Nursing staff received prior training through theoretical and practical sessions on proper use, sterile connection/disconnection technique, and replacement criteria for the neutral valves.

The catheter lock protocol was the same during both periods. A low-concentration sodium heparin solution (1,000 IU/mL) was used after each catheter use to maintain patency and prevent thrombus formation.

Allocation Method
This study was not randomised, as it was a quasi-experimental before-and-after analysis based on the institutional implementation of a new protocol. The change in catheter management (introduction of CSCNV) was applied institutionally and simultaneously across the entire unit on a specific date, which excluded the possibility of individual intervention assignment. The comparison was made between data collected during the 12 months following the implementation of the new protocol and the 12 months prior, thus ensuring a fixed temporal criterion that avoided targeted patient selection. To minimise potential selective assignment biases, all consecutive patients meeting the inclusion criteria in both periods were included, with no exclusion based on clinical characteristics or outcomes. Furthermore, data were obtained electronically through the electronic health record system, which ensured objective and systematic collection of variables.

Blinding
Both participants, the nurses administering the intervention, and the researchers assessing the outcomes were aware of the participants' assignment to the studied alternatives.

Unit of Analysis
The unit of assignment was the TCVCs of the patients recruited during the study. Of note, each catheter replacement was counted as a new unit of analysis, so the same patient could contribute more than one catheter during the study period.

Variables
CRBs were collected during both study periods. CRB was defined as a clinical picture compatible with sepsis, without another apparent infectious focus, when the following diagnostic criteria were met[12-14]:

1. Presence of clinical signs of systemic infection, such as fever, chills, or hypotension, in a catheterised patient.
2. Microbiological confirmation by at least two positive blood cultures: one obtained from the catheter lumen and one from a peripheral line, with isolation of the same microorganism in both.
3. Absence of an alternative infectious focus to explain the clinical picture.
4. Blood cultures drawn within 2 hours of symptom onset.

CRB data corresponding to both study periods were collected. The incidence rate of bacteraemia was calculated as the number of CRBs / TCVC follow-up days per 1,000, for each study period.

Evaluation of catheter dysfunction was performed by analysing technical parameters collected during each HD session, in accordance with KDOQI[15] and Spanish multidisciplinary group vascular access guidelines[16]. The indicators considered were:

- Arterial pressure (AP): desirable AP values were considered to be between -200 and -250 mmHg.
- Venous pressure (VP): desirable VP values were considered to be between 100 and 250 mmHg.
- Effective blood flow (Qb): desirable flows were considered to be ≥ 300 mL/min.
- Dialysis adequacy (Kt): calculated using ionic dialysance by the HD monitor. Desirable Kt values were defined as > 45 L in men and > 40 L in women.

Measurements were systematically performed during the period of each catheter's use, considering all records obtained during HD sessions.

Statistical Analysis
Regarding the technical parameters of the catheter (VP, AP, Qb, and Kt), these were evaluated only during the period with CSCNV use. Quantitative variables were described using measures of central tendency (mean, median) and

dispersion (standard deviation), according to the nature and distribution of the data. Qualitative variables were expressed as absolute and relative frequencies (%). For desirable and undesirable value parameters, 95% confidence intervals were calculated using the Wilson method, suitable for small samples. Additionally, a TOST (Two One-Sided Tests) equivalence test was applied, using the Welch-Satterthwaite method for calculating degrees of freedom, to verify that the combined means of each variable were within the acceptable limits defined by KDOQI guidelines[15].

To evaluate the clinical efficacy and technical operating parameters of the catheters, all devices included in the study were considered, with no loss to follow-up recorded in the database. Comparison of CRB incidence before and after CSCNV implementation was performed using a difference of proportions test, applying a z-test for rate comparison. Given that CRB events were infrequent, a Pearson regression model adjusted for the number of catheter-days as an exposure variable was additionally used to confirm the robustness of the obtained results.

No multivariate adjustments were made because the study design (before-and-after with universal protocol application) did not involve comparisons between subgroups or control of independent variables. However, clinical parameters were analysed stratified by sex to consider possible physiological differences.

A statistical significance level of $P<0.05$ was adopted for all tests. Statistical analysis was performed using R software, version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

Ethical Considerations

The study was approved by the Clinical Research Ethics Committee for Medicines (CEIm) of Girona on July 13th, 2022, with approval code 11/2022. All patients were verbally and in writing informed about the study's purpose and provided their written informed consent. Participation was voluntary, and patients could withdraw at any time.

The confidentiality of data for patients participating in the study was maintained according to the provisions of Organic Law 3/2018, of 5 December, on Personal Data Protection and Guarantee of Digital Rights (LOPDGDD). The study was conducted in accordance with the Ethical Principles established in the most recent version of the Declaration of Helsinki (19th World Medical Assembly, 1964) or the Good Clinical Practice Standards, always applying the norm that offered the most protection to the patient.

RESULTS

During the study period, 62 TCVCs (all Palindrome™ Precision H17 type) corresponding to 55 adult patients were analysed **(figure 1)**, with a distribution of 42% men and 58% women, and a mean age of 65.2 ± 12.3 years. In the 'before' period, 6,418 catheter-days were analysed, while in the 'after' period, 12,970 catheter-days were recorded.

During the 'before' period (CSCNV use), 4 episodes of CRB were documented in a total of 6,418 catheter-days, corresponding to a CRB rate of 1.25 episodes per 1,000 catheter-days. In the 'after' period (direct connection), 2 episodes were recorded in 12,970 catheter-days, yielding a CRB rate of 0.15 episodes per 1,000 catheter-days. The difference between both periods was statistically significant ($P=0.047$).

Regarding TCVC dysfunction technical values, as shown in Table 1, a statistically significant difference in VP between sexes was revealed, with a higher proportion of compliance in women ($P=0.01$). No significant differences by sex were observed in AP, Qb, and Kt, although a non-significant trend towards greater compliance in women was evident. It is worth noting that, despite this trend, the mean Kt in litres was significantly higher in men ($P<0.05$). Qb was adequate in 89.1% of cases.

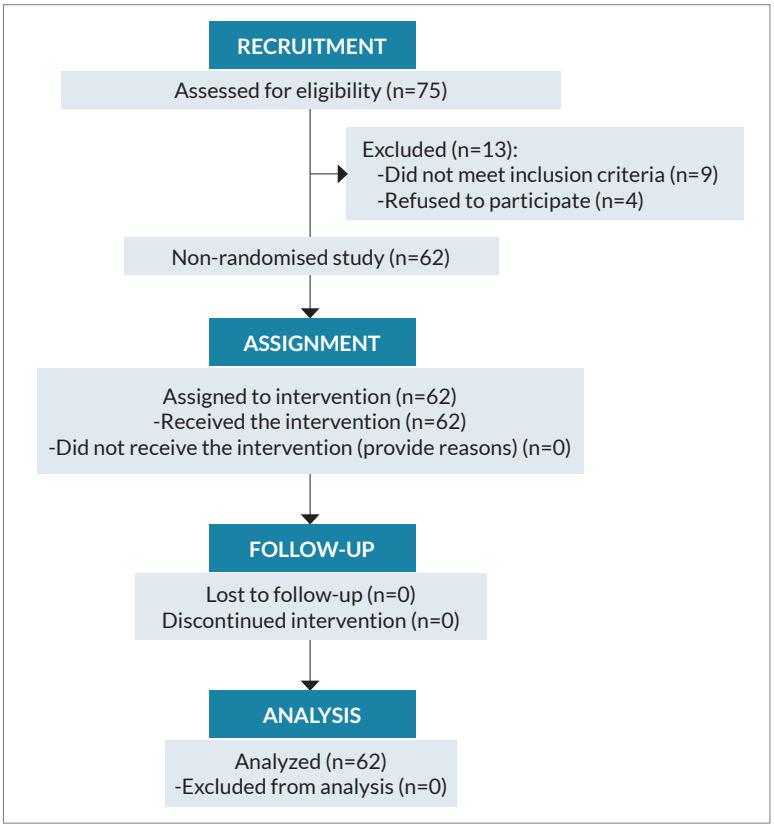

Figure 1. Participant Flow Diagram based on the TREND (Transparent Reporting of Evaluations with Nonrandomised Designs) statement.

Lladó-Barragán M, et al. htpps://doi.org/10.37551/S2254-28842025015

Table 1. Comparison of Dialysis Parameter Adequacy as Indicators of TCVC Dysfunction, by Period (n=62) and by Sex (Men n=26, Women n=36).

Parameter	Group	Desirable Value n (%)	Undesirable Value n (%)	95%CI	p
Venous Pressure	Total	61 (98.3%)	1 (1.7%)	96.2–100	0.01
	Men	25 (96.1%)	1 (3.9%)	89.7–100	
	Women	36 (100%)	0 (0%)	100–100	
Arterial Pressure	Total	62 (100%)	0 (0%)	100–100	–
	Men	26 (100%)	0 (0%)	100–100	
	Women	36 (100%)	0 (0%)	100–100	
Kt (mean)	Total	25 (40.3%)	37 (59.7%)	48.2–54.2	0.33
	Men	10 (38.5%)	16 (61.5%)	44.9–55.1	
	Women	15 (41.7%)	21 (58.3%)	46.5–53.5	
Kt (median)	Total	33 (53.3%)	29 (46.7%)	48.3–55	0.47
	Men	12 (46.1%)	14 (53.9%)	43–55	
	Women	21 (58.3%)	15 (41.7%)	46.5–53.5	
Blood Flow	Total	59 (95.2%)	3 (4.8%)	90.1–100	0.09
	Men	24 (92.3%)	2 (7.7%)	83–100	
	Women	35 (97.2%)	1 (2.8%)	91.6–100	

N: number; **%:** percentage; **95%CI:** 95% confidence interval.

No adverse effects directly attributable to the use of CSCNVs were recorded during the study period. No technical complications related to their use were documented either.

DISCUSSION

In the present study, a reduction in the CRB rate was observed after the incorporation of CSCNVs for CVCs in patients on HD treatment via a TCVC. These findings support the hypothesis that the use of devices designed to reduce catheter lumen manipulation can positively impact CRB prevention. This effect has been previously documented by Albalate et al[19] and Crehuet et al[20], who highlighted that correct manipulation of catheter connections, along with the use of appropriate devices, can significantly limit the entry of microorganisms through one of the main critical points of contamination: the connections.

In addition to the device *per se*, organisational factors, such as specific training of healthcare personnel, the availability of safe disconnection systems, and an adequate patient/nurse ratio, may have contributed to the observed effect. This multifactorial nature has also been noted in previous studies such as those by Cobo et al[21] and Bouza et al[22], who reported reductions in CRB rates when using CSCNVs instead of conventional caps or direct connections. Furthermore, Martin et al[23] reported that the use of chlorhexidine for disinfection of catheter hubs was equally effective, achieving a CRB rate of 1.8 per 1,000 catheter-days.

Regarding the clinical parameters analysed (VP, AP, and Kt), the results were consistent with those reported in previous research on CSCNV use. No statistically significant differences were observed in VP and AP before and after CSCNV implementation, although slight increases with no clinical relevance were recorded. As for the Kt value, overall results were considered adequate; however, in the subgroup of male patients, 61.5% presented a volume below 45 L, suggesting suboptimal dialysis adequacy in this group during the post-intervention period.

The results of the present study are consistent with previous evidence. Bonkain et al[24] in a randomised clinical trial, demonstrated that the use of a CSCNV significantly reduced both catheter dysfunction and CRB rates vs a control group. Similarly, Brunelli et al[25] observed, in a retrospective study, a significant decrease in CRB incidence with the use of the Tego™ connector, a needle-free and closed-system device. Guembe et al[26] reinforced these findings by showing a reduction in bacterial colonisation of catheters with the use of the same connector, although without significant clinical differences in CRB incidence, suggesting a potential early protective effect.

Other studies have also provided relevant evidence. Weiss and Qureshi[27], through a quality improvement initiative, reported a notable reduction in CRB rates after the introduction of a new CVC cap, highlighting the value of these interventions in real clinical contexts with high variability in care practices. For their part, Brunelli et al[28], in a multicentre cluster clinical trial, provided solid evidence on the efficacy of various devices, including the Tego™ connector, confirming its superiority over conventional techniques.

In a less explored context, the study by Nau et al[29] offered a paediatric perspective by evaluating the use of ClearGuard HD® in children undergoing HD. The results also showed a reduction in infections, extending the potential benefit of these devices to traditionally underrepresented populations.

Overall, the available evidence, including that from the present study, supports the use of CSCNVs for HD as a possible strategy to reduce bacteraemia in patients with TCVCs. Several limitations should be considered when interpreting these results. Firstly, it is a single-centre study, which limits the generalisation of results to other institutions with different organisational, infrastructural, or population characteristics. Additionally, as a retrospective design, there is a risk of case loss due to incomplete or inaccurate records in clinical information systems, which could introduce selection bias. Another aspect to consider is the possibility of temporal biases, given that data were collected over a specific period without control over possible changes in clinical practices, management protocols, or population characteristics over time, which could have influenced the observed results. Likewise, a concurrent control group was not included, which limits the ability to establish direct comparisons between the intervention (use of a neutral valve) and other alternatives or previous practices. This makes it difficult to attribute the observed effects exclusively to the evaluated intervention. Although the retrospective design minimises the risk of the Hawthorne effect, as there was no active intervention during data collection, the possibility of changes in the behaviour of healthcare personnel during the period in which the devices were introduced or consolidated cannot be completely ruled out, especially if there were parallel training or institutional changes, which could have influenced the quality of care and the outcomes.

As future considerations, to strengthen the evidence and overcome the above-mentioned limitations, firstly, it is suggested to conduct multicentre studies that include the participation of different types of institutions and care contexts. Furthermore, it is essential to design prospective research using more robust methodologies, such as cluster randomised trials.

In conclusion, the evidence gathered, both in the present study and in the specialised literature, supports the use of needle-free connectors and CSCNVs as an effective strategy to reduce the incidence of CRB in HD patients with TCVCs. Despite differences in exposure (catheter-days) between the compared periods, the magnitude of the observed decrease suggests a possible beneficial association between CSCNV use and the prevention of infectious events, consistent with available evidence.

From a functional perspective, no clinically relevant alterations were observed in parameters such as AP or VP, although a significant difference by sex in VP was identified, and suboptimal Kt values in the male subgroup, highlighting the importance of individualised monitoring of dialysis adequacy.

Collectively, CSCNVs should be considered an integral part of infection prevention bundles in HD units, especially for patients with long-term catheters or those with any risk factor for developing CRB.

Conflict of interest
None declared.

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