Comparison of the adequacy of dialysis and urea recirculation in patients with symmetrical tip and stepped tip catheters on chronic hemodialysis

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Abstract

Introduction: In Mexico, approximately 120,000 patients with chronic renal failure require HD replacement therapy. Angio access to HD can be temporary, semipermanent, and permanent. Semipermanent catheters have more remarkable survival, greater extracorporeal blood flow, and less recirculation. Different designs in the termination of the catheters (symmetrical tip and stepped tip) are associated with the percentage of recirculation and the adequacy of dialysis. The objective of this study was to compare the adequacy of hemodialysis in catheters with a symmetrical tip coated with heparin and silver against a stepped tip in patients on chronic hemodialysis with previous angioaccess.

Methods: Patients were randomized into two groups, defined as group one, in which the heparin-silver-coated catheter with a symmetrical tip was placed, and group two, patients with a stepped-tip catheter, considering the presence or absence of stenotic sequelae. During the follow-up, the dialysis dose was evaluated (through Kt/V, percentage reduction of urea, and blood recirculation). The results were assessed through X2, t student, and U Mann–Whitney with the statistical package SPSS version 21.

Results: In the period from April to June 2017, 38 patients were included. Thus far, 28 patients have completed the follow-up period, 15 from group 1 and 13 from group 2. The reported KT/V was 1.14 for group 1 and 1.28 for group 2, as well as the urea reduction percentage of 61 and 63 for groups 1 and 2, respectively (P =0.25). The recirculation rate was reported at 2.97 for group 1 and 1.96 for group 2 (P =0.34).

Conclusion: In the present study, there are no differences in the dialysis dose and the percentage of urea recirculation in catheters with symmetrical tips and stepped tips, so cost–benefit research is imperative.

Keywords:

MESH: Renal Dialysis; Renal Insufficiency, Chronic; catheters; Blood Urea Nitrogen
The arteriovenous fistula continues to be the angioaccess of choice in hemodialysis due to its low incidence of complications and high survival; however, the patient's comorbid conditions (peripheral vascular, heart failure, and diabetes) are not always suitable for the construction of a fistula. Therefore, the demand for hemodialysis catheters has increased with a report from the United States of between 13 and 23% [1]. An alternative to the native arteriovenous fistula is the arteriovenous graft or prosthesis, usually constructed of polytetrafluoroethylene (PTFE) material [2].

A high incidence of complications has been reported from the use of vascular catheters, the most frequent being infection and thrombosis, which indicates the need for improvement in catheter design. There are currently a wide variety of catheters available. Regarding thrombosis, using polyurethane or Carbote (a polycarbonate/polyurethane copolymer) instead of silicone has decreased its incidence since the polyurethane catheter allows better catheter resistance and softness, as well as a larger internal diameter. A more significant number of cases of infection have also been reported in silicone-based catheters [3], and carbonate has been reported to be resistant to chemicals (for example, iodine, peroxide, or alcohols), which increases the longevity of the catheter [3]. In addition, the use of antimicrobial coatings or anti-thrombogenic surface coatings (antibiotic or silver ion coating, using an antibiotic ointment at the exit site, and antimicrobial blocking) has been added to decrease the rate of infections and prevent thrombosis. [4].

Different studies in Mexico, inconsistent with the DOPPS study, indicate that close to 50% of patients do not have a permanent VA and begin the HD program through a central venous catheter (CVC).

VA dysfunction and thrombosis cause the most significant consumption of resources in the population with chronic kidney disease (CKD) because of the high use of CVCs at the beginning of HD conditions, the possibilities of future vascular access with high percentages of initial failures after the creation of FAVs, especially the cephalic radius, and deficiencies in the detection of preventable VA dysfunctions in the prevalent population.

Temporary catheters are only recommended for four weeks according to DOQI guidelines; however, there are patients in our care population in whom this time interval is prolonged [3]. Many of them also have comorbidities that make it difficult to place a semipermanent angioaccess or a previous history of central venous access and its sequelae, such as venous stenosis that makes it impossible to put a catheter and its proper functionality given the high recirculation rate. Some of them even require endovascular therapy due to the degree of stenosis, which is recommended when the percentage of stenosis exceeds 60% of the caliber of the blood vessel [5].

Blood flow is a parameter that determines the quality of dialysis, requiring a flow greater than 350 ml/min to achieve adequate hemodialysis. To improve this parameter, the tip was modified after optimizing the catheter lumen. [3, 7].

Models have recently been created that modify the type of catheter tip, with a symmetrical spike and a stepped lead, reporting a lower recirculation rate in the symmetrical tip since it increases the contact of both ends with the vascular wall, which, in turn, also improves blood flow [8].

Mingxu Li et al. [9] compared the vascular accesses available on the market, symmetrical tip, staggered tip, and AVF, with a 4-year follow-up of 148 patients who were randomized to compare the accesses with each other, finding that the catheter tip Symmetrical handles higher blood flows, better dialysis dose, unlike the stepped-tip catheter, similarly in thrombotic events the percentage of patients with symmetrical tip was 30.6% compared to the stepped-tip catheter where the rate is increased to 46.5% and decreases to 5.4% in patients with AVF. This is done through how the catheter is designed; the cutting of the symmetrical tips is carried out through a laser that reduces the possibility of coagulation and, therefore, its dysfunction.

In a randomized study of 239 patients with a symmetrical-tip catheter, 2-month survival for the catheter was 90.6% and 68.8% for a stepped-tip Hemostar catheter; In terms of blood flow, the one with the symmetrical tip was better, as well as in terms of thrombotic events, giving the same explanation for the laser cutting of the tip, in both thrombolytics such as urokinase and plasminogen activating factor were used with success. The Hemostar merited greater use of thrombolytics than the one with a symmetrical tip. The need for catheter replacement for any reason was higher in the Hemostar at 76.4% compared to the balanced tip at only 71.3% at a 24-month follow-up [10].

In the follow-up of a catheter, apart from the mentioned characteristics, its functionality must be evaluated through blood flow, which must be above 350 ml/min, with arterial pressure greater than -250 mmHg and venous pressure above 250; all values below this tell us about dysfunction [4].

Grooves or lateral holes also play an essential role in the function of the catheter. The symmetrical tip catheter has tracks created with a laser that avoids the rough edges of the tip that facilitate the anchoring of clots to the tip, a situation that confers to this catheter the reduction of the thrombogenic phenomenon [4, 11].

The objective of the present study was to compare the dialysis dose through KT/V, the percentage of urea reduction, the percentage of urea recirculation of the catheter and the measurement of blood flow of the catheter with a symmetrical tip coated with heparin and silver against the stepped-tip catheter in chronic hemodialysis patients with previous angioaccess with and without venous stenosis.

Materials and methods

Study design
The present study is experimental. The source is prospective.

Scenery
The study was carried out in the hemodialysis unit of the Hospital de Especialidades “Dr. Bernardo Sepúlveda,” Siglo XXI National Medical Center, in Mexico City. The study period was from July 1, 2017, to January 31, 2018.
Participants
The inclusion criteria were patients with stage 5d chronic kidney disease with superior central venous angioaccess. The exclusion criteria were patients with CKD with sequelae or occlusion of superior major veins not amenable to repellency using endovascular therapy and patients with active infectious processes. Cases that did not complete the follow-up period and those who revoked informed consent were eliminated.

Variables
The study variables were blood flow, immediate catheter functionality, Kt/V, urea reduction percentage, angioaccess recirculation percentage, and dialysis dose. The groups were controlled for the following variables: sex, age, etiology of renal failure, and body mass index.

Sample selection
Patients who met the previously mentioned inclusion criteria, required the placement of a tunneled hemodialysis catheter, had patent upper central venous access, or were susceptible to endovascular treatment were selected. The patients were staged by performing phlebography of both upper extremities and ultrasonographic tracking in different modalities, grayscale, color, and pulsed Doppler, to assess the superior central veins. According to the results of these studies, patients with prominent upper veins of typical characteristics are classified as having mild stenosis that does not require angioplasty or stent placement and moderate to severe stenosis that requires angioplasty or stent placement. They were assigned one of the two catheters, symmetrical tip and heparin and silver coating or staggered tip, alternately according to the order of arrival and according to the group they were in according to the findings referred to in the imaging studies so that both groups were evenly distributed.

Data sources/measurements
The source was direct; surveys and measurements were carried out on patients upon admission to the study before the hemodialysis session. Additionally, consultation with the institutional clinical history was needed. The information was treated confidentially; no personal data were included to identify the study subjects.

Once the vascular access was placed in the hemodynamics service under the previously established protocol, the patients were followed-up for two weeks (6 sessions) by the nephrology service, evaluating the following parameters:

I. The maximum blood flow of the catheter was evaluated in the third hemodialysis session. Blood flow was assessed at the beginning of the session (60-90 minutes after hemodialysis), considering that the maximum tolerated blood flow will be lower than that which produces a counterproductive increase in cardiac output or vascular steal.

II. The recirculation test was performed in the fourth hemodialysis session. Such a test is usually quantified by measuring the urea concentration at three locations: the arterial and venous lines and the systemic circulation. It was calculated according to the following formula: % Recirculation = [(A - S)/(V - S)] x 100, where A, V, and S refer to the concentrations of urea nitrogen (BUN) in the arterial, venous, and systemic samples, the latter being taken from a vein of the arm contralateral to that of the vascular access. The measurement was carried out under the following protocol:

The test was performed 30 minutes after starting dialysis without active ultrafiltration:
1. - The pump speed was set to 500 ml/minute (or the maximum possible).
2. - Samples were extracted from the arterial (A) and venous (V) lines.
3. - The blood flow rate was immediately reduced to 120 ml/minute.
4. - After reducing the blood flow, the pump was stopped for precisely 10 seconds.
5. - An arterial line clamp was placed just above the extraction port.
6. - The systemic arterial sample (S) was extracted from the arterial extraction port.
7. - The line clamp was removed, and dialysis and ultrafiltration were resumed.

Subsequently, blood urea nitrogen was measured in samples A, V, and S, and the recirculation (R) percentage was calculated using the formula.

III. The fifth hemodialysis session measured the Kt/V and urea reduction rate. Urea Kt/V was measured using the mathematical model of predialysis urea and postdialysis urea. The recommended procedure consists of documenting the gender, weight, and height for the calculation of the volume of urea distribution, and the analysis of the total body water is carried out with the Watson formula under the following protocol: [11]

1. The 1st predialysis sample was taken before the start of treatment (urea), and the blood sample was obtained before the injection of saline, heparin, or another potential diluent.
2. The 2nd sample (postdialysis) was taken at the end of the treatment; the blood flow was reduced to 100 ml/min for 15 seconds, and the model was extracted from the arterial line. The formula of Daugirdas (1995) was used:

\[
\text{Kt/V} = \ln (1 - \text{TRU})
\]

\[
\ln (\text{TRU}) = \ln (R - 0.008 \times t) + (4.35 \times R) \times 0.55 \times \text{UF/V}
\]

\[
R = 1 - \text{TRU}
\]

\[
\text{UF/V} = \text{BUN} \times \text{UF} \times \text{BUN} \times \text{HDF} \times 100
\]

\[
\text{T} = \text{duration of treatment in hours}
\]

\[
\text{ln} = \text{natural negative logarithm}
\]

\[
\text{UF} = \text{weight loss in kilograms}
\]

\[
\text{V} = \text{volume according to Watson's formula}
\]

\[
\text{Kru} = \text{renal clearance of urea}
\]

In the case of residual renal function = 4.5 x \text{Kru}/V = contribution of the Kru to the weekly Kt/V (add) [11].

IV. The lumens are heparinized at the end of the session with 5000 IU heparin according to the length of the catheter.

In the case of presenting dysfunction during hemodialysis sessions characterized by flows less than 300 ml/min, arterial pressure less than -250 mm/Hg, or venous pressure greater than 250 mm/Hg, catheterography was performed to determine the cause of dysfunction. Twenty milliliters of nonionic iodinated contrast medium was administered in each lumen, acquiring serial images with bone.
subtraction at the thoracic level. In an intraluminal thrombus, catheter patency was performed with a hydrophilic guidewire. If dysfunction persisted despite said maneuver, catheter replacement was evaluated in the same topography or new venous access. In the case of clinical data of infection, cultures of secretion and blood cultures were taken, as well as initiation of antimicrobial treatment.

**Biases**

To avoid possible interviewer, information, and memory biases, the principal investigator kept the data at all times with a guide and records approved in the research protocol. Observation and selection bias was avoided by applying the participant selection criteria. All the clinical and paraclinical variables of the period above were recorded. Two researchers independently analyzed each of the records in duplicate, and the variables were recorded in the database once their concordance was verified.

**Study size**

The sample was nonprobabilistic, census type, where all possible cases of the study period were included. The patients collected were randomized to one of the study groups.

**Quantitative variables**

Descriptive statistics were used. The results were expressed on a scale of means and standard deviation. Categorical data such as sex are presented in proportions.

**Statistical analysis**

Inferential statistics are used. Data are presented with measures of central tendency and dispersion. Qualitative variables are presented as absolute numbers and percentages; quantitative variables are presented as medians and standard deviations. According to the distribution, they were compared with Student’s t test and the Mann–Whitney U test (parametric and nonparametric, respectively). The statistical significance level was $P < 0.05$. The statistical package used was SPSS 28.0 (IBM Corp. Released 2021, IBM SPSS Statistics for Windows, Version 28.0, Armonk, NY: IBM Corp).

**Results**

**Participants**

Thirty-eight analyzable patients entered the study, and 28 completed the study (Figure 1).

**General characteristics of the sample**

The median age of the population was 55.7 years (range: 17–91), and the female gender predominated in both groups. In the etiology of kidney disease, diabetic nephropathy prevailed in 60.7%, as shown in Table 1.

Regarding previous vascular accesses per patient, the median was 2.21 catheters in both groups (range 2–4), as shown in Table 1. Moderate stenotic venous sequelae were evidenced in six patients evaluated by phlebography and Doppler ultrasound, that did not require angioplasty or stent placement (Table 1).

The most frequent approach was the right jugular vein (89.3%), as shown in Table 2. Once the catheter was placed and after 24 hours of surveillance for complications, the patients received their first hemodialysis session where $Q_{\text{Smax}}$ one was measured, which was $439 \pm 41$ and $400.3 \pm 45$ ml/min for groups one and two, respectively. In the second measurement, $Q_{\text{Smax}}$. 2 was $449 \pm 42$ and $433 \pm 63$ ml/min for groups 1 and 2, respectively, without statistical significance at both times.

![Figure 1. Flowchart of the participants.](image-url)

| Table 1. Descriptive variables of the study groups. |
|---|---|---|---|
|  | Group 1 | Group 2 | $P$ |
| Age (years) | 54 | 57.6 | 0.53 |
| Sex |  |  |  |
| Male | 4 | 5 | 0.43 |
| Female | eleven | 8 |  |
| Size (cm) | 159.2 | 158.2 | 0.75 |
| Weight (kg) | 66.4 | 60.3 | 0.31 |
| Etiology |  |  |  |
| Type 2 diabetes | eleven | 6 | 0.15 |
| Another cause | 4 | 7 |  |
| No. Previous catheters | 2.26 | 2.15 | 0.56 |
| venous sequel | 4 | 2 | 0.48 |
Tip catheters, respectively.

Dialysis dose was measured by KT/V and percent urea reduction and a percent recirculation measurement during sessions three to six after catheter placement. The KT/V, percentage of urea reduction, and rate of recirculation of the general population and both groups (without statistical significance) are shown in Table 3. Angioaccess dysfunction occurred in seven (25%) of 28 patients who underwent permeabilization and rearrangement procedures depending on the cause of the dysfunction, which predominated the catheter attached to the atrial wall (Table 4).

### Table 2. Location of access and extracorporeal flow.

<table>
<thead>
<tr>
<th>Location</th>
<th>Group 1 n=15</th>
<th>Group 2 n=13</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right jugular</td>
<td>12</td>
<td>13</td>
<td>0.09</td>
</tr>
<tr>
<td>Left jugular</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Maximum blood flow</td>
<td>439</td>
<td>400</td>
<td>0.12</td>
</tr>
<tr>
<td>1st session</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd session</td>
<td>449</td>
<td>433</td>
<td>0.35</td>
</tr>
</tbody>
</table>

Two of the patients who presented catheter dysfunction required replacement with a catheter with the same characteristics. Although there were no major venous thrombosis events, three cases of per catheter thrombosis were reported in group 2 patients, and no events were reported in group 1 patients.

### Table 3. Dialysis Dose and Vascular Access Recirculation Rate

<table>
<thead>
<tr>
<th>Group 1 n=15</th>
<th>Group 2 n=13</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>KT/V</td>
<td>1.14</td>
<td>1.28</td>
</tr>
<tr>
<td>% reduction of urea</td>
<td>61</td>
<td>63</td>
</tr>
<tr>
<td>% recirculation</td>
<td>2.97</td>
<td>1.96</td>
</tr>
</tbody>
</table>

Regarding the comparison of the dialysis dose between these two tunneled catheters, the percentage of urea reduction had an average of 62% with a report of 61 and 63 for groups 1 and 2, respectively, with a KT/V of 1.14 and 1.28 for groups 1 and 2, adequate according to the recommendations of KDIGO 2015 (1.4, minimum 1.2), contrary to other studies [9-11] that report a KT/V of 1.28 ± 0.20 and 1.39 for the stepped-tip catheter. ± 0.24 for the symmetrical tip catheter \( P = 0.02 \), a higher dialysis dose.

A lower recirculation rate has been reported in the symmetrical tip catheter since it increases the contact of both tips with the vascular wall, which also improves blood flow [9]. In this study, there was no significant difference between the two groups, with an adequate recirculation percentage in both catheters for the type of angioaccess (tunneled) according to the 2015 KDIGO recommendation (less than 10%).

Vascular access dysfunction in our study was 25%, with the need for replacement in two patients (7.1%), much lower in the stepped-tip catheter group than that reported by Hans Van Der Meersch with the Hemostar catheter of 76.4%. However, the follow-up of the study above was 24 months.

In the study group, a single event of infection of the catheter insertion site was presented in group 1; however, there were cases of fever in other patients, resulting in negative cultures, so they were not classified as having catheter-related fever. It must be considered that approximately 5 to 10% of the cultures may be harmful to atypical or slow-growing germs.

Our study's strength is that other analyses have not considered the presence of stenotic venous sequelae in patients with a symmetrical tip catheter, so the results could not be translated to our population.

One of the areas for improvement of the study thus far is the limited number of the sample, so a more significant number of patients will be included for analysis. Just as it is also required to give a longer follow-up to evaluate long-term functionality, a situation in our population could be more difficult considering the dynamics of the patient and procedures such as subrogation.

### Discussion

In the present randomized clinical study in which two tunneled catheter tip designs divided into two groups were evaluated, in this population of patients, the etiology of renal disease, as in the Mexican people in general, the most frequent cause continues to be diabetic nephropathy, which I represent 60.7%.

In the present study, there was a history of 2.23 temporary catheters, which generated moderate stenotic venous sequelae. This situation has yet to be evaluated in other studies; however, there was no impact on functionality and dialysis dose up to the time of this preliminary evaluation.

The functionality of both catheters was evaluated using maximum blood flow without finding a significant difference in both catheters, different from what was reported by Hans Van Der Meersch et al., who said in their study a greater blood flow for the symmetrical tip catheter than for the staggered tip catheter (333 and 304 ml/min, \( P = 0.001 \)), and by Mingxu Li et al., who reported a blood flow of 323 ± 35 and 418 ± 44 \( P = <0.001 \) for the stepped-tip and symmetrical-tip catheters, respectively.

### Conclusion

There were no differences in the dialysis dose given by the symmetrical tip and stepped tip catheters, and the recirculation percentage in both catheters was adequate, with no significant difference. According to our results, it seems that one or the other design (symmetrical tip and stepped tip) offers an additional advantage at the end of the study. If these results are corroborated, a cost–benefit study could be justified in subsequent analyses.

### Abbreviations

- Qs: Blood flow.
- QB: Extracorporeal flow.
- K: Clarification.
- T: Time.
- V: Volume of distribution of urea.
Supplementary information
Supplementary materials have not been declared.

Acknowledgments
Does not apply.

Author contributions
Annel Ortiz Vilorio: Data curation, Formal analysis, Fundraising, Research, Methodology, Project management, Resources, Software, Writing – original draft.
Maria Inés Gil Arredondo: Conceptualization, Supervision, Validation, Visualization, Writing: review and edition.
Pedro Trinidad Ramos: Conceptualization, Supervision, Validation, Visualization, Writing: review and edition.
All authors read and approved the final version of the manuscript.

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