Are continued policies of prioritizing native vascular access in patients on hemodialysis programs useful?

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Abstract
The guidelines recommend establishing native vascular access as opposed to prosthetic or catheter-based access despite information relating to its effectiveness being scarce from a patient-orientated perspective. We analyzed the effectiveness of a continued policy of native vascular access (CPNVA) in patients undergoing hemodialysis. A retrospective, observational study, including 150 patients undergoing hemodialysis between 2006 and 2012 at our center, and who underwent a CPNVA. Statistical analysis was based on treatment intention. In 138 patients (92%), the first useful access (FUA) was native, and in 12 patients (8%), it was prosthetic. In 50 patients (33.3%), more than one procedure had to be carried out in order to achieve FUA. The probability of dialysis occurring via a FUA was 67.1% and 45.3% at 1 and 5 years respectively. Over the follow-up period (mean time = 30 months), 84 patients (56%) required repairs or new access, extending the effectiveness of the CPNVA to 88.3% and 73.2% at 1 and 5 years respectively. The effectiveness of the CPNVA was reduced if the patient: required a catheter initially (HR: 3.6, p = 0.007); in cases of initially elevated glomerular filtration rate (HR: 1.1, p = 0.040); in cases of history of previous access failure before FUA (HR: 3.9, p = 0.001); and in female patients (HR: 2.4, p = 0.031). The long-term effectiveness of a CPNVA is high. However, the percentage of patients requiring diverse procedures in order to achieve FUA and the need for re-interventions yield the necessity to optimize preoperative evaluation and postoperative follow-up.

KEYWORDS
AV access, dialysis, follow-up, native vascular access, patient-orientated, survival

1 INTRODUCTION
Chronic renal disease represents a public health issue due to its high incidence rate, prevalence, and morbidity/mortality, particularly in patients who require a renal substitution treatment. One of the factors determining the morbidity/mortality of patients undergoing hemodialysis is the vascular access that they have [1].
Establishing vascular access for useful and long-term hemodialysis has been a constant cause of concern for nephrologists and vascular surgeons since the creation of the first primary arteriovenous anastomosis in 1966, by Brescia [2]. Nowadays, arteriovenous fistula at wrist or at elbow still represents the initial access for many patients. As opposed to native techniques, arteriovenous prostheses started to be used for vascular access in the 1960s, becoming the procedure of choice for many years in the United States and Canada. This tendency began to see correction from 1997, when the National Kidney Foundation started to publish the KDOQI Guidelines [3]; the objectives of the Guidelines included improvement of hemodialysis patients management.

One of the main recommendations of the KDOQI Guidelines is to establish native vascular access as the preferred method over other procedures (AV prosthesis, catheters), given its reduced complication rate and more prolonged patency. However, the majority of publications that underpin this recommendation refer to studies that have not been carried out under an intention-to-treat premise, and that frequently have as their sole objective to describe the patency associated with specific surgical techniques, more than their usefulness for hemodialysis from a global perspective (patent access, which allows for adequate dialysis, without complications) [4–7]. As a result, information on the real effectiveness of a continued policy of native vascular access (CPNVA) as proposed by the KDOQI Guidelines is relatively scarce.

As such, the objective of our study was to evaluate the long-term effectiveness of a CPNVA in our patient population undergoing a program of hemodialysis due to end-stage chronic renal disease.

2 | PATIENTS AND METHODS

One hundred and fifty patients were included in the study retrospectively, all undergoing hemodialysis due to end-stage chronic renal insufficiency at the Hospital del Mar (Barcelona) between January 1, 2006 and December 31, 2010. Four patients were excluded who had been incorporated into the hemodialysis program, having vascular access that was established in other centers; one patient was excluded who was indicated, from the start, for permanent vascular catheter insertion.

Referrals for patients to the Vascular Surgery Service for assessment regarding dialysis access were carried out from the advanced chronic renal disease consultations, where patients presented with a deterioration in renal function with a mean glomerular filtration rate (as per MDRD-4) of less than 20 mL/min/1.73 m², in accordance with international consensus. An initial native access was indicated on a preferential basis in all patients over another type of access (catheter, prosthesis, arteriovenous) based on a physical examination. As a general rule, a fistula at wrist of the non-dominant limb was indicated. Subsequently, where there is a need for it, this would be carried out at elbow and, finally, on the dominant limb following the same criteria. Informed consent was obtained from all patients in writing, with approval by the Ethics Committee of the Hospital del Mar.

Over the entire course of follow-up, and in the case of any complication, dysfunction or thrombosis of the access impeding adequate dialysis, a new autologous technique was decided on, wherever possible, as a corrective measure, otherwise as a new access. Over the study period, there was no protocol of the systemic vascular hemodynamic investigations in these patients. Finally, there was an indication for implantation of an arteriovenous prosthesis or permanent catheter only in cases where it was assumed that all possibilities for a native access had been exhausted.

Vascular access considered to be useful for hemodialysis was: patent; functionable; free of complications; it allowed for effective hemodialysis in low recirculation conditions; it had correct urea clearance parameters; it had no pressure-related issues (arterial and venous). These usefulness criteria were taken into consideration for both the first useful access (FUA) and in a cumulative form for CPNVA. In this respect, “end of follow-up with effective CPNVA” was considered to be when the patient was able to undergo dialysis via an autologous access until death, transplant or study end date; whereas “end of follow-up with ineffective CPNVA” was considered to be when the patient required an arteriovenous prosthesis or permanent catheter to continue in the dialysis program. Initial failures of the CPNVA were considered to have occurred in patients who finally required initiation of hemodialysis via an arteriovenous prosthesis (AVP) due to it being impossible to create a FUA.

Statistical analysis was performed using the SPSS program (Statistical Package for the Social Sciences, version 25, SPSS Inc). The effectiveness curves were calculated for hemodialysis of the FUA and the CPNVA in the form of survival curves. Previously, the predictive factors for reduced effectiveness of hemodialysis were analyzed using the Kaplan–Meier test and Cox regression, both for the FUA and the CPNVA. All values of $p < 0.05$ were considered to be statistically significant.

Of the 150 patients, 101 (67%) were male. The mean age at the start of dialysis was 62.9 ($\pm$14.9) years. 38.7% were diabetic; 14.7% presented with a history of coronary heart disease; and 39% with a history of cardiac insufficiency. The mean baseline glomerular filtration rate at MD
the point in time when the first vascular access (for hemodialysis) was created was 10.2 ± 4.4 mL/min/1.73 m². 52.7% of patients required a temporary or tunneled catheter in order to start hemodialysis before achieving an FUA. The clinical characteristics of the study population are described in Table 1.

### Table 1 Clinical characteristics of the study population

<table>
<thead>
<tr>
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<th>n (%)</th>
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<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>62.9 ± 14.9</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>101 (67)</td>
</tr>
<tr>
<td>Female</td>
<td>49 (33.1)</td>
</tr>
<tr>
<td><strong>High blood pressure</strong></td>
<td>100 (66.7)</td>
</tr>
<tr>
<td><strong>Diabetes mellitus</strong></td>
<td>58 (38.7)</td>
</tr>
<tr>
<td><strong>Ischemic cardiopathy</strong></td>
<td>22 (14.7)</td>
</tr>
<tr>
<td><strong>Cardiac failure</strong></td>
<td>58 (38.7)</td>
</tr>
<tr>
<td><strong>Cardiac arrhythmia</strong></td>
<td>35 (23.3)</td>
</tr>
<tr>
<td><strong>Cerebrovascular disease</strong></td>
<td>24 (16)</td>
</tr>
<tr>
<td><strong>Cancer</strong></td>
<td>15 (10)</td>
</tr>
<tr>
<td><strong>First useful access (FUA)</strong></td>
<td></td>
</tr>
<tr>
<td>Native</td>
<td>138 (92)</td>
</tr>
<tr>
<td>Arteriovenous prothesis</td>
<td>12 (8)</td>
</tr>
<tr>
<td><strong>Number of failed accesses before the FUA</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>102 (68)</td>
</tr>
<tr>
<td>One or more</td>
<td>48 (32)</td>
</tr>
<tr>
<td>Hemodialysis program started by temporal catheter</td>
<td>79 (52.7)</td>
</tr>
</tbody>
</table>

*Main age ± standard deviation.

### Table 2 Predictors of failure of CPNVA with p value (p) and hazard ratio (HR) with a 95% confidence interval

<table>
<thead>
<tr>
<th>Associated factors to CPNVA survival</th>
<th>p value (p)</th>
<th>Hazard ratio (confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>0.031</td>
<td>2.4 (1.1–5.1)</td>
</tr>
<tr>
<td>Presence of previous temporal catheter</td>
<td>0.007</td>
<td>3.6 (1.4–8.9)</td>
</tr>
<tr>
<td>Failed native access prior to FUA</td>
<td>0.001</td>
<td>3.9 (1.7–8.5)</td>
</tr>
<tr>
<td>Initially high glomerular filtration rate</td>
<td>0.004</td>
<td>1.1 (1–1.2)</td>
</tr>
</tbody>
</table>

Abbreviations: CPNVA, continuous policy of native vascular access; FUA, first useful access.

### 3 RESULTS

A FUA was achieved in 138 patients (92%). In 50 patients (33.3%), at least one access was required prior to achieving an FUA. The radiocephalic fistula (RCF) represented the first autologous fistula carried out in 103 patients (68.7%), also being the FUA in 43.3% of cases. In 35 patients (31%), the FUA was a fistula at elbow. Finally, in the case of 12 patients (8%) it was necessary, following repeated unsuccessful attempts to achieve native access, to implant an arteriovenous prosthesis in order to start renal substitution therapy. We achieve a mean follow-up of 30 months (maximum follow-up: 105 months).

The probability of a patient maintaining hemodialysis via the FUA, including the group of patients who required an initial arteriovenous prosthesis as immediate failures, was 67.1% at 1 year, and 45.3% at 5 years.
This probability was reduced significantly among patients who had required a temporary catheter in order to start hemodialysis (HR: 0.54, \( p = 0.018 \)), and in the case of patients with higher baseline glomerular filtration rate values (HR: 1.8, \( p = 0.026 \)).

Over the course of follow-up, surgical repairs were carried out and/or new native accesses were created in order to treat dysfunctions or losses of the FUA in 84 patients (56%); it was possible to increase the effectiveness of the CPNVA at 1 and 5 years by 88.3% and 73.2% respectively (Figure 1b).

The main predictors of failure of CPNVA were: female sex (HR: 2.4, \( p = 0.031 \)); history of temporary catheter at initiation of the hemodialysis program (HR: 3.6, \( p = 0.007 \)); increased baseline glomerular filtration rate values (HR: 1.1, \( p = 0.040 \)); and, of course, presenting with at least one failed access prior to the FUA (HR: 3.9, \( p = 0.001 \)). These data are summarized in Table 2.

Accordingly, at 5 years, the probability that a female patient would maintain dialysis via a native access is 59%, compared to 81% for a male patient (Figure 2a); the probability is 90% if there is no history of prior temporary catheter, compared to 56% where this has been necessary (Figure 2b); and 86.3% in patients who did not require any previous access, compared to 48% in those patients who required one or more prior accesses (Figure 2c). It is noteworthy that a marginally significant association was found between reduced effectiveness and the presence of diabetes mellitus; however, no significant correlation has been identified in the sample with respect to age or other comorbidities.

4 | DISCUSSION

The scientific literature on accesses for hemodialysis is particularly prolific in articles relating to concrete surgical or endovascular techniques, which are particularly useful for evaluation of each of their specific contributions with respect to others, but which often do not allow for an overview. In contrast, natural history studies allow for quantification and analysis, from a global and patient-orientated perspective, of the main problems
associated with the durability and usefulness of accesses, the probability of reintervention, or the possibility of eventually having a permanent catheter. Our study, in line with previous studies, contributes to a better understanding of the real effectiveness of a CPNVA as set out by the KDOQI Guidelines, and provides specific information on two aspects that have scarcely been the subject of analysis to date: the number of interventions necessary to achieve useful access; and the durability/usefulness of a preferential policy of autologous accesses over the long term, carrying out an analysis based on treatment intention.

With respect to the characteristics of the study population, age on initiation of dialysis, and sex distribution, there were no great differences as compared with these aspects in studies in the Mediterranean region [8]. In previous studies in the United States, a substantially lower age on initiation of dialysis could be identified (around 56 years old), as well as higher rates of comorbidities, such as ischemic cardiopathy [7]. In fact, increased survival has been described in patients on hemodialysis in the Mediterranean region as compared to other regions of Europe or the United States, which highlights the importance of extending the maximum life of autologous vascular accesses [9, 10].

Following the recommendations from the aforementioned Guidelines, in our center the RCF represented the initial autologous access created in almost 69% of patients, with this type of fistula becoming the FUA in almost half of these. The autologous access at elbow (including humerocephalic and humerobasilic) represents the first useful native access in almost 49%. In the series described by Solesky et al. [11], the first access created is radiocephalic in 20%.

In our population sample, the percentage of patients who initiated hemodialysis via a temporary catheter or tunneled catheter was 52.7%, a proportion which is similar to data described in other studies and in the KDOQI Guidelines [3, 4, 8, 10, 12]. It is well known that starting hemodialysis via a temporary catheter or tunneled catheter is independently associated with worse results when creating native vascular accesses. Ethier et al. describe the most important factor associated with initial catheter use as the late referral to specialist, which varies according to the country [12].

Nowadays, it seems to be in doubt that use of a catheter by itself could increase the mortality rates in the hemodialysis patients. Brown et al. [13] suggest that the best baseline characteristics of the patients undergoing a native vascular access are related with a low mortality, compared to the group of patients in which we decide to implant a permanent catheter, whom usually are more frail and elderly. However is widely known the highest rates of hospitalizations [14] and severe infections [15] in hemodialysis population are described in patients with a catheter.

In our group, 33% of patients required creation of more than one arteriovenous access in order to achieve a first useful native access. In similar studies, around half of patients required more than one procedure in order to finally achieve a valid native access for dialysis [16, 17]. We were successful in creating a permanent first access for hemodialysis as an arteriovenous fistula in 92%, a percentage much higher than the target of 65% set by the Fistula First Initiative [16, 18]. Despite this, 8% of our patients presented as initial failures under this policy, requiring an arteriovenous prosthesis to be inserted. This fact contrasts with the prevalence of dialysis via prosthetic access in the United States at around 20%, according to data from 2013 [18].

At 1 year, 67% of the patients continued to receive hemodialysis via the FUA. Patel et al. and Biuckians et al. describe similar rates of primary patency at 1 year [19, 20]. Thanks to successive treatment of dysfunctions and thrombosis relating to the arteriovenous fistula by means of repair procedures or creation of new native access, we were able to achieve a probability of our patients undergoing dialysis via a native access of 88.3% and 73.2% at 1 year and at 5 years respectively. To the best of our knowledge, these data have not previously been described from this perspective and it seems, however, to be information that should be highlighted, not only for comparison with other therapeutic strategies, but also to inform patients who are entering dialysis programs.

With regard to factors that negatively influence survival of native accesses, in the studies reviewed, age, female sex, and presentation of diabetes are cited as associated factors [12, 18]. In our study, the factors which were associated with worse results in CPNVA in a statistically significant way were: female sex; history of temporary catheter to initiate dialysis; presenting with one or more failed access prior to the FUA; and elevated glomerular filtration rate at the time when the access was created. With regard to the factors of female sex and history of previous catheter, the worsened progress may be attributed to poorer quality of the vascular network. Either et al. [12] have described an increased rate of failures of accesses with increased time delay between creation and first cannulation (it can be understood that patients subject to procedures to create an access too early have better clearing at the time of surgery), although the causes associated with this failure are unknown. Other parameters were analyzed, such as the presence of diabetes mellitus, age, hemoglobin levels at the time when access was created, as well as other...
comorbidities: no statistically significant differences were identified in the survival curve for the accesses.

One of the major limitations of this study is its retrospective design, which has limited the number of preoperative variables that it has been possible to include without loss of information or inclusion of poor quality data. Similarly, the small number of patients included in the analysis could have limited the detection of predictive factors to include only those that showed a close association with later dysfunction of the access. This limitation, however, is common to the other studies that have evaluated the results, similarly from a patient-orientated perspective [11, 17].

The ultrasound evaluation of the arteriovenous capital constitutes a very important tool in the choice of the type of vascular access. In our case, the lack of this information constitutes another limitation. Therefore, the aim of our study was to prioritize a follow-up as long as possible, so we decided to include patients from 2006 to 2012, assuming that on these periods the ultrasound preoperative evaluation was not performed by routine in our center. We are analyzing a more recent cohort in which the ultrasound evaluation could have a decisive role in the indication of the vascular access.

Moreover, prosthetic access was also considered as an initial failure of our patient—focused program and was not excluded from the initial analysis in spite that their results could be, a priori, more favorable. In our opinion, their inclusion showed a true global vision and real burden of the CPNVA strategies in our institution. However, the inclusion of these prosthetic accesses could be interpreted as another limitation or bias selection and could detect some differences in the predictive factors involved.

Finally, we have data available to us on the incidence of a catheter on initiation of dialysis, but not on the prevalence of dialysis via catheter in our study population: this information would be interesting to obtain as a quality measure relating to overall care to the dialysis patient. Similarly, only those patients who were evaluated by the vascular surgeon have been included in the study, and as such, it does not take account of the small proportion of the patient population which, due to their overall condition, are maintained on a dialysis regime via catheter with no view to creating an autologous or prosthetic vascular access.

5 | CONCLUSIONS

From a patient-focused perspective, the long-term effectiveness of a continued policy of native vascular access is high. However, the proportion of patients requiring more than one access before achieving an first useful access, the elevated number of cases requiring a catheter to initiate dialysis, and the frequent need to repair or carry our new autologous accesses over time bring to light the importance of optimizing clinical evaluation both preoperatively and during follow-up. Detecting predictive factors of subsequent dysfunction may be of great benefit for this purpose. New studies are necessary, however, to evaluate whether adding complementary examinations (such as Doppler ultrasound scan) to the clinical examination might contribute to improving continued policy of native vascular access results.

CONFLICT OF INTEREST

The authors of this article have declared that there are no potential conflicts of interest relating to the content of this article.

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