

# Factors associated with early fistula failure: how to improve it

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## ABSTRACT

**Introduction:** Around the world, risk factors for fistula failure have been considered in vascular access planning in order to improve results. However, primary fistula failure rates seem to be increasing. Considering this, we conducted a study to identify relevant factors for early fistula failure in a Portuguese cohort with end-stage kidney disease. **Subjects and Methods:** Retrospective case-control study which included patients from a hospital center who underwent fistula construction between 2012 and 2015. Patients with fistula failure at 6 weeks were matched with consecutive controls in a proportion of 1:1. Clinical and laboratory data were retrieved. Multiple regression analysis was performed to identify factors associated with early complications. **Results:** Total of 100 predialysis patients with fistula failure at 6 weeks. Mean age of 67.7±11.9 years; most were women (n=54). Factors associated with overall risk of complications were distal location of fistula (OR 2.8; p<0.05) and diabetes mellitus (OR 3.8; p<0.05). Congestive heart failure (OR 7.2; p=0.06) was associated with a tendency for greater risk of inflow complications. **Conclusions:** In this cohort, despite improvements in vascular access planning, traditional risk factors still have a significant impact on fistula outcomes. The role of “new” factors is still undefined and further studies are needed. An adequate patient education, an organized vascular access program with nurses, nephrologists and surgeons with expertise, with systematic use of Doppler ultrasound, are key factors for better outcomes.

**Key-Words:** Uremia; risk factors; early fistula failure

## INTRODUCTION

A well-functioning vascular access is essential for a proper dialysis. The native arteriovenous fistula (AVF) has proven to be the preferred choice, since it has longer primary patency rate, requires fewer interventions and is associated with the lowest incidence of morbidity and mortality. However, a major problem is the unpredictability of successful maturation<sup>1-4</sup>. Around the world, traditional risk factors for fistula failure have been considered in vascular access planning in order to improve results. However, a recent meta-analysis that examined patency rates of AVFs

in 62 cohorts published from 2000 to 2012 showed an increase in primary AVF failure rate (23%) comparing to the previous years (15%)<sup>5</sup>. Higher prevalence of female gender, distal fistula location and presence of diabetes mellitus are some factors suggested as possible contributors for this failure rate. Age or peripheral artery disease could not explain differences in AVF outcomes. Other important issues such as vessel diameter and quality, surgical expertise and differences in vascular access surgical training and facilities, which were not considered, may also have impacted on results. In fact, the authors highlighted the complexity around vascular access choice,

evaluation and management. Different study definitions and methods are important limitations that need to be addressed in order to reach further valid conclusions. Also, a clearer view of the potential new players in fistula maturation is necessary. New insights have shown that uremic state and use of antithrombotic agents may play a role in fistula maturation. Uremia stimulates neointimal hyperplasia and smooth muscle cells proliferation promoting vascular stenosis, so it has been hypothesized that a higher uremic milieu present in more advanced renal failure may negatively impact AVF outcomes<sup>6-8</sup>. The use of antithrombotic agents, such as aspirin, clopidogrel or warfarin has been associated with a reduction in early vascular stenosis and thrombosis with an important effect in modulation of the altered vascular biology<sup>3,6</sup>. It's not clear if different etiologies of kidney disease, particularly diabetic kidney disease, would have influence in outcomes<sup>9</sup>.

Considering this, a study was conducted in a Portuguese cohort of patients who underwent AVF construction recently in order to identify factors associated with greater risk for primary failure.

## SUBJECTS AND METHODS

### Study setting and population

This was a retrospective case-control study designed to incorporate patients undergoing AVF construction between 1.1.2012 and 31.12.2015 in a single Portuguese center. All patients were predialysis patients. Those who had a failure-to-mature fistula at 6 weeks after construction were matched with consecutive controls in a proportion of 1:1. Functional mature fistula was defined according to the NFK KDOQI 2006 vascular access guidelines. A failure-to-mature fistula was one with early complications which compromised its ability to be puncturable. Early complications were defined as inflow complications (arterial disease, stenotic lesions at or just beyond the anastomosis) or outflow complications (stenotic lesions in the venous segment).

### Data collection

In our center, patients with advanced chronic kidney disease (stage 4 and 5) are referred to a vascular access consult to create a vascular access. This consultation

is organized and performed by a multidisciplinary team (a nephrologist, a vascular surgeon and a specialized nurse). The same vascular surgeons who lead the consultation construct the fistulas. In a first observation, relevant clinical data concerning age, gender, race, primary renal disease, cardiovascular and metabolic co-morbidities, previous central catheters, cardiac and vascular interventions, presence of pacemaker, anticoagulation and antiplatelet use are recorded. Those data are incorporated with information obtained by Doppler ultrasound assessment of vasculature in order to guide the choice of AVF creation, with minimum vessel diameters of 2 mm. A second observation is made after 10 days of AVF construction to remove surgical suture and to confirm at least the presence of thrill. A third observation is made after 6 weeks of construction to confirm adequate maturation. For those which failed to mature, we try to identify potential causes and how to manage them. Posterior interventions and re-evaluations are scheduled. All this information is recorded and available in a digital database, which was reviewed. Variables retrieved for study analysis are expressed in Table 1.

**Table 1**

Variables retrieved for study analysis

Demographic data	Age, Gender, Race
Cause of End Stage Kidney Disease (ESKD)	Hypertension, Diabetes, Cystic Disease, Chronic Glomerulonephritis, Others
Comorbidities	Cerebrovascular Disease, Hypertension, Diabetes Mellitus, Congestive Heart Failure, Peripheral Artery Disease
Use of antithrombotic agents	Aspirin, Clopidogrel, Warfarin and Acenocoumarol
Previous vascular procedures and vascular access data	History of previous arteriography/angioplasty, vein diameter before AVF construction, localization of AVF, inflow or outflow complications.
Laboratory data	Creatinine, urea, and glomerular filtration rate (GFR, by CKD-EPI formula) 30 days before fistula construction.

### Statistical analysis

Comparison of baseline characteristics between two groups was made with the chi-squared and Mann-Whitney tests. Multiple logistic regression analysis was used to identify significant predictors of early complications. The following variables were categorized into analysis: age <65 years versus ≥65 years; diabetic versus nondiabetic kidney disease; creatinine <4.5 mg/dL versus ≥4.5 mg/dL; urea <150 mg/dl versus ≥150 mg/dL and GFR <15 ml/min/m<sup>2</sup> versus ≥15 ml/min/m<sup>2</sup>.

## RESULTS

### Characteristics of patients

A total of 100 patients with fistula failure at 6 weeks were identified and matched (1:1). All patients were Caucasian. Global mean age was 67.9±12.8 [23; 90] years; most were female patients (n=105; 52.5%). Table 2 summarizes the main characteristics of groups.

**Table 2**

Baseline characteristics of study and control group

Characteristic	Early Fistula Failure Group	Control Group	p value
Mean age, SD (range)	67.7±11.9	68.2±13.7	0.1
Female Gender, n	54	53	0.5
Cause of ESKD, n	–	–	–
Diabetes	53	36	0.05
Hypertension	13	10	0.7
Glomerulonephritis	11	20	0.3
Cystic Disease	7	7	0.5
Others	17	27	0.2
Co-morbidities, n	–	–	–
Hypertension	88	86	0.3
Diabetes mellitus	78	47	0.01
Congestive Heart Failure	34	30	0.6
Peripheral artery disease	30	18	0.04
Cerebrovascular disease	23	14	0.07
Previous vascular procedures, n	11	8	0.5
Antiplatelet drugs, n	35	37	0.9
Anticoagulation drugs, n	7	3	0.4
Vascular Access Data, n	–	–	–
Mean vein diameter (mm), SD	1.9±0.6	2±0.5	0.6
Proximal location of AVF	25	37	0.06
Distal location of AVF	76	63	0.07
Inflow Complications	72	–	–
Outflow Complications	28	–	–
Mean creatinine (mg/dL), SD	3.9±2.9	3.8±1.8	0.6
Mean urea (mg/dL), SD	160±48	152±49	0.7
Mean GFR, SD	10.9±3.7	11.5±3	0.2

### Risk Factor for Poorer Outcomes

Factors associated with overall risk of complications were distal location of AVF (OR 2.8; p<0.05) and diabetes mellitus (OR 3.8; p<0.05). Antithrombotic agents were not associated with better results. When analysis was performed considering the type of complication, presence of congestive heart failure (OR 7.2; p=0.06) was associated with a tendency for greater risk of inflow complications. In this group of patients, the distribution

of proximal (16 vs. 19) and distal (14 vs. 14) fistulas was similar between groups. No factor associated with risk of outflow complications was identified.

## DISCUSSION

Understanding how to optimize the primary patency of fistulas is fundamental to improving survival and quality of life of patients<sup>1-3</sup>. Education and proper vascular access programs are pillars to obtain good results<sup>4,10</sup>.

The authors present a model of vascular access program which has allowed a reduction in central catheter use with increments in fistula number and patency rates in their center. Four steps have been identified in order to increase the rates of a functioning mature access: process of care (early education, vascular access team and timely surgery referral); preoperative evaluation; surgical strategy and monitoring programs<sup>10,11</sup>.

An education program must start in the early phases of chronic kidney disease and should be continuous, multidisciplinary, structured, and adjusted to patient goals and preferences<sup>11</sup>. Without proper information, patients are unable to make an informed decision regarding the dialysis access choice. In fact, patient knowledge and education can predict modality and vascular access choice. Low initial rates of AVF use reported in United States and Canada could be partially explained by poor knowledge of vascular access choices and lack of education during follow-up<sup>12</sup>. Predialysis educational programs performed by a multidisciplinary team (including a dedicated nephrologist and nurse) were associated with decreased mortality and longer time until dialysis initiation, which would give more time for fistula creation and maturation<sup>13,14</sup>. Vascular access education is also associated with increased fistula use at dialysis initiation<sup>11,12</sup>. The nephrologist should focus on the systematic and patient-level barriers in achieving a functional AVF, with emphasis on creation, maturation and cannulation that consider patient's goals and preferences<sup>11</sup>. Information about the importance of vein preservation with prevention of injury to vessels used in AVF construction should be given. Written pamphlets can be of great use. Avoidance of PICCS (peripherally inserted central catheters) and subclavian catheters to minimize central vein stenosis and other complications must be outlined<sup>17</sup>. Several entities have developed "save my veins" bracelets or "medic-alert bracelet" to remind patients and to alert health professionals<sup>11,12</sup>.

The creation of a successful vascular access team must also promote staff education and expertise. Nurses and vascular surgeons assume a central role in this part, since a deficit in skills in the area of assessment/cannulation and surgical construction can have devastating consequences<sup>10-13</sup>.

The preoperative evaluation is a cornerstone. The integration of patient and vascular characteristics allows defining the type of access and surgical strategies. There are some factors that can't be changed, such as patient comorbidities. Diabetes mellitus, congestive heart failure and distal localization of FAV were associated with risk for early complications in this study, which is consistent with current literature<sup>9,15</sup>. Peripheral artery disease, which reflects vascular burden, was also significantly more frequent in early fistula failure group. This study wasn't powered enough to detect if primary kidney disease or the use of anti-thrombotic agents can affect fistula outcomes. Some small studies<sup>16-22</sup> showed encouraging results with use of aspirin, clopidogrel and dipyridamole, with beneficial effects on endothelium. Similarly, anticoagulant drugs may delay vascular occlusion, but is proven that they do not attenuate the pathophysiologic process, so adjunctive therapy is required. This study is also one of the first in vivo investigations trying to establish an association between uremia and early fistula failure. The authors hoped that the obtained results could help to clarify the question about the better time to refer to AVF construction. A pro-mitogenic effect of uremia in human vascular smooth muscle cells was observed in a recent investigation performed by Aitken et al.<sup>6</sup> with higher serum urea levels being related with poorer fistula outcomes. These results were not supported by our findings. Despite similar glomerular filtration rates, time of data collection was different (30 days versus 2 weeks before AVF construction) such as the medium urea levels, may be because of distinct laboratory methods of measurement. Also, the study presented by Aitken had many flaws and the authors assumed that there were many confounding issues. Other factors like patient comorbidities, hemodynamics, vascular characteristics, surgical skills and vascular planning probably have had a superior impact in AVF maturation<sup>5,6,9</sup>.

Likewise, it is possible that other uremic toxins may play a more important role than urea. In fact, some authors have suggested that timing of access creation may be important to AVF outcomes but this point is not clear<sup>23-27</sup>. In DOPPs study<sup>23</sup>, longer time from referral to surgical evaluation or longer time from creation

of vascular access to cannulation was associated with less probability of starting dialysis with a fistula. The UK renal Association recommends referral when patient is at kidney disease stage 4, considering primary disease and probable rate of decline. The guidelines from the Canadian Society of Nephrology are similar (creatinine clearance 15-20 ml/min/m<sup>2</sup>) and 2006 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines suggest referral "at least 6 months before the anticipated need for dialysis". In this cohort, managed by an organized program, FAV creation with lower glomerular filtration rates, reflecting a more advanced kidney disease, did not contribute to poorer outcomes.

Importantly, there are some disadvantages related with an earlier FAV construction, such as increased cardiovascular morbidity and mortality and adverse psychological factors<sup>9,11,12</sup>. Further studies are needed to clarify the right time of AVF construction.

Regarding all this, complex decisions are very common. As an example, the benefits of a more proximal fistula in high risk patients must be balance with risk of complications like deleterious cardiac impact and steal syndrome, particularly in elderly<sup>2,9</sup>. Also, recent evidence has been shown that grafts or even central catheters may not be inferior to AVFs in fragile patients, patients with severe comorbidity burden or in the very elderly. Functional status, illness experiences, health priorities and life expectancy are fundamental issues to be considered<sup>28-30</sup>.

Several scores and predictive models of arteriovenous maturation are being developed in order to help reach more accurate decisions<sup>31-35</sup>. A recent trial about preoperative computer simulation for planning of vascular access surgery in hemodialysis patients is being conducted<sup>35</sup>. Noninvasive markers of endothelial function such as peripheral arterial tonometry (PAT), which provides a measure of pulse wave amplitude during reactive hyperemia, can also be used to estimate vascular health and predict outcomes<sup>36</sup>.

Using Doppler ultrasound for vascular territory assessment is a valuable tool and is probably underused. This image technique is the only one that allows simultaneous visualization of vascular anatomy and its blood supply. Functional data can also be retrieved, like pulse wave velocity (PWV) and flow mediated dilatation (FMD) of the brachial artery. Pulse wave velocity reflects arterial stiffness and is an independent predictor of cardiovascular mortality. FMD is a measure of the change of brachial artery diameter in response to

artery cuff occlusion and subsequent nitric oxide release, allowing the evaluation of macrovascular endothelial cell function<sup>36,37</sup>. This is also an exam that can be directly executed by the surgeon who will be creating the vascular access, and this is an important advantage. International guidelines recommend its use in all AVF candidates<sup>31</sup>. However, this is a technique that is time-consuming and requires an experienced examiner and special equipment. Effort must be made in training and education in this area<sup>31</sup>. Surgical technique also requires profound theoretical and practical knowledge. Avoidance of acute angles, hypotension and low blood flow can help to prevent early fistula failure<sup>11,34</sup>. Assisted maturation, which regards operative salvage techniques in early dysfunctional fistulas, plays an important role in achieving functional maturation and long-term patency, as an alternative or in conjunction with other minimally invasive procedures<sup>38</sup>. Referral to an experience center or centralization of the proceedings can help to overcome the gap in vascular access surgical expertise and facilities<sup>38</sup>.

The monitoring and surveillance program is critical for prevention of early failure and sustenance of long-term patency. There are a number of methods described in the literature: physical examination (PE); measurement of access blood flow (Qa); ratio intra access pressure/mean arterial pressure and recirculation rate, among others. Many of these methods have good accuracy to detect stenosis and have been shown to improve AVF patency<sup>10</sup>. A well-designed program should be able to detect early dysfunction and a close monitoring of the progression of a known stenosis or other vascular complication, allowing a timely referral for surgical or endovascular intervention<sup>16</sup>. Nurses are key players in this program. Nephrologists who follow these patients should be proficient in the skills of VA monitoring. Any abnormality should make it necessary to maintain a close clinical monitoring or refer for another VA consultation for further assessment<sup>10</sup>.

Finally there are important limitations to this study. It is a relatively small cohort of patients, with data collected retrospectively and the results need to be validated in a large, prospective, multicenter analysis. Patient data were taken from digital processes and there may have been a bias related to missing coded diagnostics. The study only includes vascular morphologic measures (vascular diameter). Furthermore, it did not consider all the factors proven to be associated with fistula maturation, which could have modified the obtained results.

## CONCLUSIONS

Despite optimization of clinical and surgical issues surrounding AVF construction, traditional risk factors such as AFV distal location, diabetes mellitus and probably congestive heart failure still play a significant role in poorer outcomes in this cohort. The role of “new” factors is still undefined and further studies are needed. An adequate patient education, an organized vascular access program with nurses, nephrologists and surgeons with expertise, with systematic use of Doppler ultrasound, are key factors for better outcomes.

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