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Clinical Utility of the WavelinQ™ EndoAVF System

Considering future options and analyzing current application in predialysis patients, basilic and brachial vein fistulas, and conditioning poor veins.

BY NICHOLAS G. INSTON, PhD

Definitive vascular access is a key element in the pathway of care for patients requiring hemodialysis. The arteriovenous fistula (AVF) was first described in 1966,[1] and although new anatomic sites and configurations have been described, few improvements in outcomes have been made.

Well-functioning autologous AVFs have demonstrated superiority over prosthetic grafts and central venous catheters (CVCs), but they are not without problems.[2-4] The failure rate of surgical AVFs is dismally high, with 28% to 53% never becoming functional for dialysis.[5]

AVFs that are never adequate for dialysis are defined as failure to mature (FTM), occurring in around 25% to 40% of cases.[6-8] Maturation is dependent on vessel remodeling and the endothelial response to dramatic changes in venous blood flow. Poor vessel selection, vessel trauma from surgical manipulation, and abnormal patterns of blood flow are all implicated as causes of FTM. Modifications to surgical techniques and devices developed to reduce FTM have been described but have not been widely adopted.[9,10]

Even when successful, AVFs have a high incidence of dysfunction and late failure from nonthrombotic causes such as aneurysm and steal syndrome or, more commonly, from stenosis and thrombosis.[11]

THE ENDOVASCULAR AVF

A recent technical advance in vascular access creation is the WavelinQ™ 4F EndoAVF System (BD; formerly everlinQ, TVA Medical). This is the next-generation device, innovating the design from its predecessor, the WavelinQ™ 6F EndoAVF System. This endovascular AVF (endoAVF) device consists of a dual magnetic catheter system with a venous and arterial catheter, which creates a fistula in the proximal forearm via a percutaneous route, without the need for surgical incision or suturing (Figure 1). The catheters can be introduced from the upper arm or wrist* in a parallel or antiparallel fashion and are guided to the creation site with fluoroscopic imaging (Figures 2 and 3). A radiofrequency energy burst creates a channel between the radial or ulnar artery and one of the adjacent paired deep veins, a previously underused creation site. Blood flows from this anastomosis through a venous perforator into the superficial veins (either the cephalic vein, the basilic vein, or both). To direct blood flow superficially, coiling the deep vein is recommended. Suitable anatomy to create this type of fistula is estimated to be present in up to 90% of the population.[12]

A GROWING CLINICAL EVIDENCE BASE

Both the 6- and 4-F systems have been investigated in several clinical studies and are commercially available in Europe, Canada, and the United States. The FLEX study was a safety and feasibility study of the WavelinQ™ 6F EndoAVF System. Results were favorable, and an endoAVF was successfully created in 32 of 33 patients. Cumulative patency at 6 months was 96.2%, and the mean time to maturation was 58 days.[13]

The FLEX study was followed by the international, multicenter NEAT study, which demonstrated a procedural technical success rate of 98% (59 of 60 patients) and a 12-month primary patency rate of 73% (88 of 91 patients) (Kaplan-Meier estimate).[14] Device- and/or procedure-related serious adverse events were reported in 8% of patients (5 of 60 patients). Eliminating the use of closure devices has been recommended, along with using a stabilization arm board. The requirement for further interventions was low at 0.46 interventions per patient-year.

Although the WavelinQ™ 6F EndoAVF System requires contrast imaging, the doses can be low and no adverse impact on kidney function in predialysis patients has been demonstrated; in fact, 76% of predialysis patients in the NEAT study did not initiate dialysis during the 12-month

*In the United States, the safety and performance of the device via arterial wrist access have not been fully established. The incidence of vessel stenosis or occlusion that occurs in the radial and ulnar arteries after arterial wrist access has not been evaluated. The endoAVF should only be created using brachial artery access. Please consult the instructions for use for indications, contraindications, hazards, warnings, and precautions.

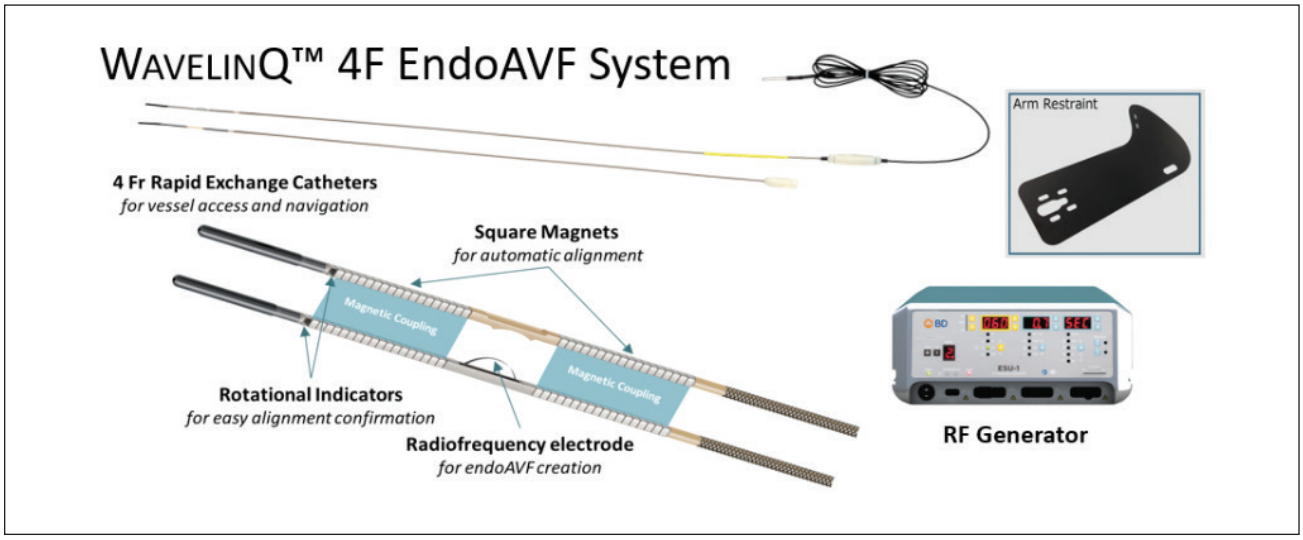

Figure 1. WavelinQ™ 4F dual catheter system for creation of endoAVFs. The device consists of an arterial and venous catheter, which are inserted via an upper arm, wrist, or antiparallel approach into the forearm vessels. They oppose magnetically, allowing a radiofrequency burst, which creates a fistula.

study follow-up, despite undergoing the fluoroscopy-based endoAVF procedure.

CONSIDERATIONS FOR USE OF THE WAVELINQ™ ENDOAVF SYSTEM

Current guidelines precede the introduction of endoAVFs and, therefore, do not include specific recommendations for when it is appropriate to choose one.[15,16] When compared with a surgical AVF cohort using matched propensity scoring, the WavelinQ™ 6F EndoAVF System demonstrated lower average first-year costs per patient-year associated with postcreation procedures.[17]

Because the WavelinQ™ EndoAVF System creates a native autologous AVF, it logically fits into the standard algorithm for AVF creation locations. The WavelinQ™ EndoAVF site is in the proximal forearm; a distal-first approach would imply use of the endoAVF when a radiocephalic AVF is not an option but prior to an upper arm fistula. However, considering the patency and low intervention rate of the WavelinQ™ EndoAVF System and the high failure rates of radiocephalic AVFs,[16] some physicians may consider creating an endoAVF with the WavelinQ™ EndoAVF System as a first option for certain patients.

Use in Predialysis Patients

Guidelines support the creation and establishment of a working AVF at the initiation of dialysis.[15,16] Despite these recommendations, the number of patients starting dialysis with a CVC is high.[18]

The WavelinQ™ 6F EndoAVF System may offer advantages for predialysis patients. The approach is minimally invasive and does not require surgery. The created fistula results in a shared flow between the cephalic, basilic, and brachial veins. This may account for the low incidence of subsequent complications. In the WavelinQ™ 6F EndoAVF System studies to date, no aneurysms and only one incidence of steal syndrome have been described, and the need for secondary interventions to maintain patency was much lower than with surgical AVFs.[13,14,17] This would be especially advantageous for predialysis patients in terms of decreasing the likelihood for multiple procedures, along with the associated contrast that may be needed to support the use of their fistula.

Because the upper arm vessels all receive blood flow from the anastomosis in the forearm, they all become potential fistula conduits and facilitate combinations of cephalic and/or basilic vein cannulation zones.

Further studies are required to assess the impact of the WavelinQ™ EndoAVF System on patients who started dialysis with a CVC, but this approach appears attractive, particularly when the consequences of a failed surgical AVF and the use of CVCs are poor, both clinically and economically.[19,20]

The Conditioning Fistula

In my experience, creation of an endoAVF with a WavelinQ™ EndoAVF System may be an option for patients with marginal superficial veins deemed not suitable for a surgical AVF. The creation of an endoAVF in the proximal midforearm vessels may be a viable option. With brachial vein coiling, blood flow can be directed into the superficial system via the perforator, which may result in superficial

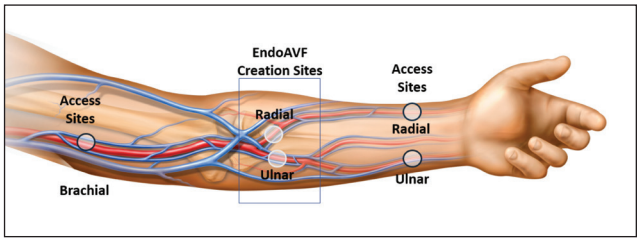

Figure 2. The catheters can be introduced from the upper arm or wrist in a parallel or antiparallel fashion and are guided to the creation site with fluoroscopic imaging. Note: In the United States, only the brachial artery should be used for arterial access. Illustration by Mike Austin. All rights reserved.

vein remodeling. This may result in superficial veins that mature sufficiently for cannulation or simply enhance the vessels such that a surgical or radiologic procedure can be subsequently employed to create a suitable autologous surgical AVF and avoid prosthetic grafts and CVCs (Figures 2 and 3).

BASILIC AND BRACHIAL VEIN FISTULAS

In my practice, the basilic vein is a useful second- or third-line access option. With good anatomy, a basilic vein fistula can be created in a single-stage procedure. However, in many cases, it is divided into two stages; the first stage is creating the anastomosis at the elbow, and then a superficialization and transposition of the basilic vein is subsequently performed at 4 to 6 weeks when the vessel has dilated and matured.

The WAVELINQ™ EndoAVF System can be used as a minimally invasive approach to the first stage of this process. The advantages over a surgical approach are that more length is available for the second-stage procedure because the anastomosis is in the forearm and there is no scar tissue at the site of mobilization (Figure 4). This may help reduce the incidence of basilic angle of transition lesions because angulation of the swing segment may be optimized.[21]

In many patients, the basilic vein communicates with the brachial veins, and a basilic vein fistula is not an option.[22,23] The WAVELINQ™ EndoAVF System may provide a suitable option for these patients because the blood flow will pass through the path of least resistance, creating a suitable conduit for superficialization and transposition. The resultant fistula may be a brachial–basilic or a transposed brachial vein alone.

LONGER-TERM OPTIONS

Data have demonstrated fewer complications and reinterventions with the WAVELINQ™ EndoAVF System compared with surgical AVFs, although long-term data are awaited.[17] A possible benefit of the split-flow WAVELINQ™ EndoAVF System is the flexibility it creates for future options. Unlike single-draining conduits, if an endoAVF has issues with the cannulation vein, the blood flow will subsequently be redirected. An example would be a postcannulation hematoma compressing the fistula vein. In this setting, the fistula will be kept open by collateral drainage and allow resolution of the issue without occlusion of the anastomosis or loss of the fistula. In the event the cephalic vein requires a tie off, the basilic and brachial veins will already have matured, allowing for an immediate solution rather than having to create a new fistula and await maturation.

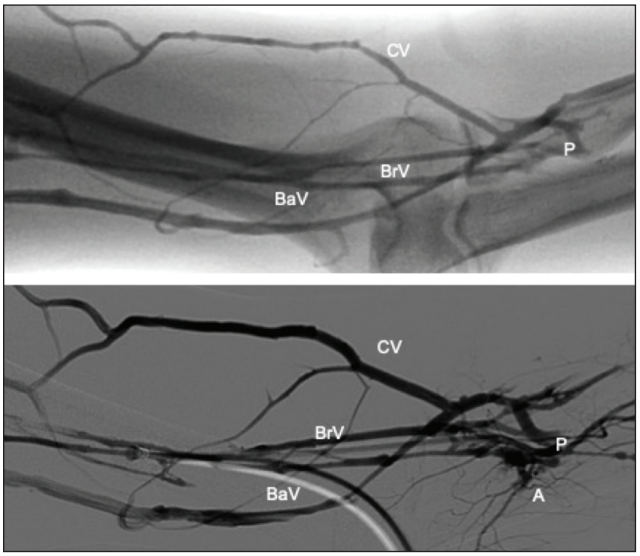

Figure 3. The upper fluoroscopy picture (top image) is a preprocedure venogram showing marginal vessels in the upper arm. The site of the perforator (P) can be seen in the proximal forearm. The bottom image was taken immediately after the creation of a WAVELINQ™ EndoAVF (A) in the same patient. The cephalic vein (CV), the basilic vein (BaV), and brachial vein (BrV) all have increased flow and the potential to mature into suitable fistula conduits, although the CV appears to be the dominant vessel in this patient.

THE FUTURE OF ENDOAVF

The introduction of the WAVELINQ™ EndoAVF System into clinical practice is welcomed. Surgical fistulas, the mainstay and gold standard of dialysis vascular access for so long, are far from a perfect option. The evidence to date supports endoAVFs created using the WAVELINQ™ EndoAVF System in terms of technical success, patency, and reduced interventions. Further benefits may be realized from this approach across various aspects of the patient pathway, from predialysis use to tertiary access options.

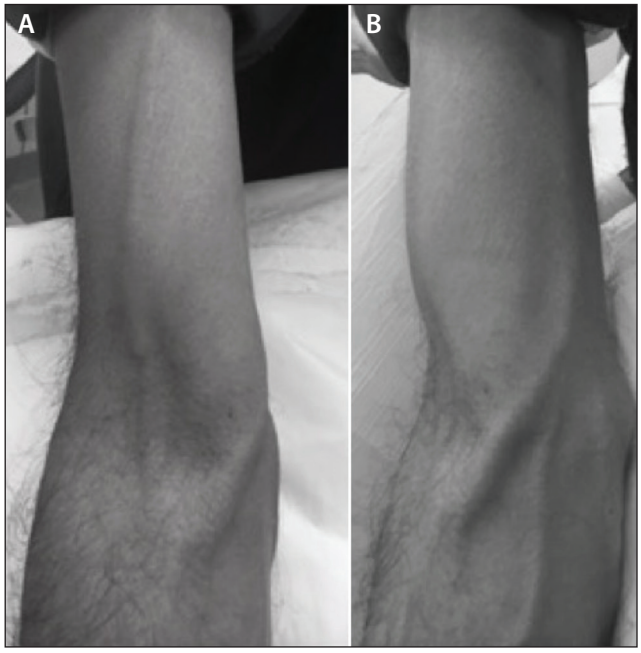

Figure 4. Clinical photographs of WAVELINQ™ EndoAVFs. Note that there is no antecubital scar and the fistula arises in the midforearm. Label A demonstrates that the cephalic and basilic vein have become suitable cannulation candidates. Label B demonstrates excellent development of the basilic vein suitable for a surgical transposition. (Picture reproduced with patients' permission.)

The endoAVF appears to offer increased opportunities in vascular access. The potential for extending options in the vascular access pathway requires further exploration to maximize their use for patient benefit. ■

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