Endovascular Arteriovenous Fistula Creation: A Single Center Experience

In depth review

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ABSTRACT

Endovascular systems represent an interesting technique for the non-surgical creation of an arteriovenous fistula (AVF) for hemodialysis. The aim was to evaluate the efficacy and the safety of the application of an endovascular system to perform AVF in ESKD patients treated at our center.

Methods. Color Doppler ultrasound was used to assess anatomical criteria for patient's eligibility. Accurate clinical and instrumental post-procedural follow-up was carried out.

Results. Endovascular AVF (endoAVF) was successfully created in 7 patients without peri-operative complications. During the procedure, coiling in the brachial vein (n = 4) and angioplasty were performed (n = 1) to divert more flow through the perforator to the superficial veins (cephalic, median cubital and/or basilic veins). Color Doppler ultrasound showed optimal 24-hour, 7-day, 30-day, 6-month and 12-month AVF flow rates. All endoAVF met maturation criteria within the first month and were successful cannulated. Primary patency rates at 4, 6 and 18 months were 100%, 85.7%, and 71.4%, respectively. Cumulative patency rate during follow-up (median 16 months) was 100%. During follow-up, 2 patients (29%) required corrective interventions with a re-intervention rate of 0.21 procedures per patient year.

Conclusions. The study confirms this alternative technique for AVF creation as safe and effective. The implementation of a well-trained team including nephrologists and interventional radiologists is crucial to obtain and maintain a well-functioning endoAVF.

KEYWORDS: Arteriovenous fistula, endovascular, hemodialysis, percutaneous, vascular access

Introduction

The choice of the optimal hemodialysis vascular access is part of the "action plan" that should be proposed and individualized for each patient with progressive chronic kidney disease (CKD) and/or with estimated glomerular filtration rate (eGFR) between 15 and 20 ml/min/1.73 m^2 (End-Stage Kidney Disease Life-Plan) [1]. Timely planning and performing vascular access are crucial to obtain a functional hemodialysis access, essential for delivering adequate dialysis, and to avoid the risk of complications related to the use of temporary central venous catheters (CVC), thus limiting the need for subsequent interventions [1, 2].

In recent years a promising option for the creation of the arteriovenous fistulas (AVF) for hemodialysis derives from the implementation of 2 innovative techniques: percutaneous (Ellipsys) or endovascular (WavelinQ) [3, 4].

By using these systems, the site of AVF creation is in the proximal forearm. Indeed, both methods take advantage of the perforating vein as a connection between the deep venous circulation and the superficial venous circulation. Although the 2 techniques use a different approach to create an AVF, both have shown promising results in terms of maturation rate and subsequent use [3, 5–11]. The WavelinQ device (BD Medical, previously EverlinQ TVA) is a system of specific 4Fr arterial and venous catheters (Figure 1) guided inside the vessel under fluoroscopy that, by using radiofrequency (RF) energy, creates an arteriovenous communication in the deep circulation of the proximal forearm. The arterialization of the superficial veins occurs through the perforating vein [7, 12]. The choice of the WavelinQ technique includes a preliminary phase of careful evaluation of the patient aimed at assessing his eligibility to endovascular AVF (endoAVF) creation with this specific system. For this purpose, an accurate mapping through color Doppler ultrasound is crucial to ensure that the anatomical criteria essential for creating the endoAVF are met [6, 7].

The aim of the study was to evaluate the preliminary data about the feasibility, the efficacy, and the safety of the application of the WavelinQ technique to perform an endovascular AVF (endoAVF) in patients with end-stage kidney disease (ESKD) undergoing hemodialysis at the Dialysis Unit of the Policlinico Umberto I Hospital, Rome, Italy.

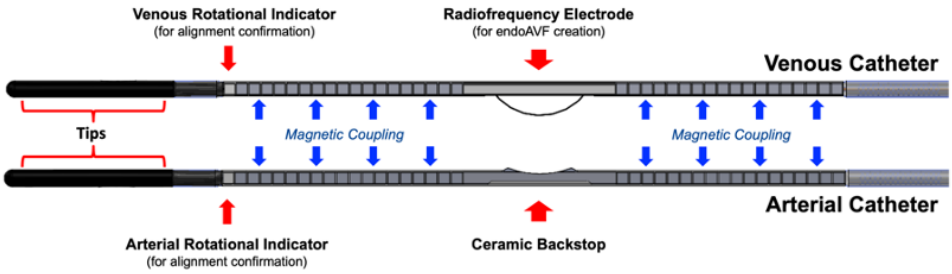

Figure 1. Main components of venous and arterial catheters of the WavelinQ device.

Patients and Methods

We performed a single-center retrospective analysis of ESKD patients who underwent endoAVF creation with the WavelinQ system between May 2023 and September 2024 at the Interventional Radiology Unit of the Policlinico Umberto I Hospital (Rome, Italy). Main data were prospectively recorded and retrospectively analyzed.

The technical success was defined as the successful completion of the procedure, as well as the intraoperative control of the AVF blood flow by ultrasound. EndoAVF maturation was defined

according to KDOQI 2019 criteria [1]. Perioperative complications have been defined as hand ischemia, bleeding, and infections.

The study was approved by the Territorial Ethical Committee of Lazio Area 1, Italy (No. 293/2025) on March 26, 2025. All participants provided written informed consent prior to participating.

Vascular mapping and procedure planning

To evaluate the eligibility of the patients for the creation of endoAVF, the vessels of both arms were accurately studied through a color Doppler ultrasound examination.

In particular, the potential access sites for the devices, the target vessels for the creation of the fistula, the presence and the adequacy of the perforating vein as a connection between the deep circulation and the superficial circulation, were carefully studied. Essential anatomical characteristics for WavelinQ system application are summarized in Figure 2. The patency and the depth with respect to the skin plane of any venipuncture sites (cephalic vein and/or basilic vein) were also evaluated. The WavelinQ system also requires that the distance between the ulnar or radial artery and their concomitant veins at the target fistula creation site is less than or equal to 2 mm. Finally, the presence of central venous stenosis and/or upper extremity venous occlusion on the same side as the planned AVF creation have been excluded. Depending on the access site considered suitable at color Doppler ultrasound examination, the parallel (same direction) or antiparallel (opposite direction) approach for the introduction of the 2 catheters has been scheduled.

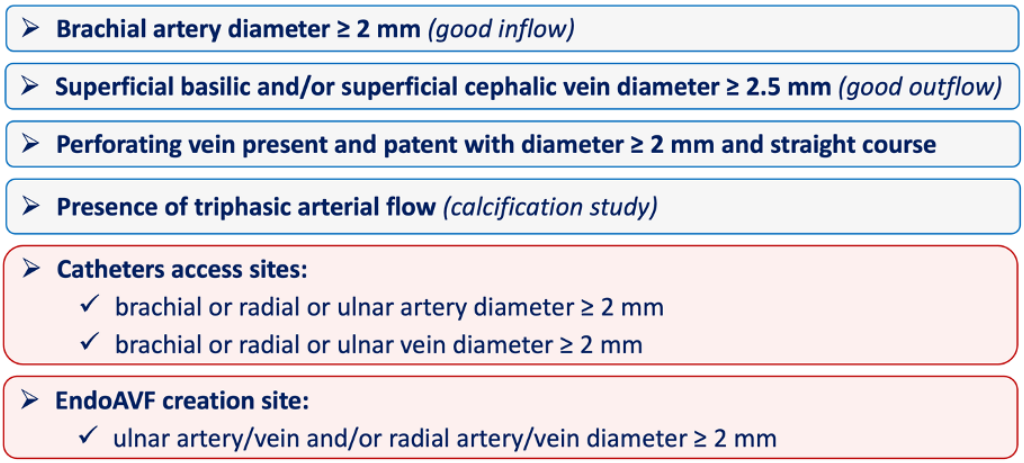

Figure 2. Main eligibility criteria for endoAVF creation.

EndoAVF creation procedure

The procedure was performed in supine position and under local or brachial plexus block anaesthesia. The arm, which was designated for the endoAVF creation, was immobilized on a side table with the palm facing upward. Under ultrasound guidance, the arterial and venous catheters were percutaneously inserted. In the case of "parallel approach", percutaneous access was obtained through the cannulation of the radial artery and its concomitant vein at the wrist or the brachial artery and its concomitant vein at the upper arm; in the case of "antiparallel approach", the access was gained through the radial artery at the wrist while the brachial vein was accessed from the upper arm. By using fluoroscopy, the catheters advanced until the target creation site was reached (Figure 3a). Once placed in proximity, the magnets of the 2 catheters attracted each other, pulling the arterial and venous vessels closer together. After evaluating the correct alignment of the magnets (Figure 3b), it was possible to deliver the burst of RF energy (60 Watts for a duration of 0.7 seconds) through the electrode in the venous catheter, thus obtaining the communication between the artery

and the vein. Then, an intraoperative arteriography was performed to verify the actual creation of the fistula (shunt of blood flow from the artery to the venous system) and to exclude any immediate complications such as blood extravasation or pseudoaneurysm formation. Moreover, the need to divert more flow through the perforator to the superficial veins (cephalic, median cubital and/or basilic veins) by embolization of the brachial vein (positioning of a coil) or by angioplasty of the outflowing veins (perforator vein, cephalic vein and/or basilic vein) was also assessed. Hemostasis after endovascular catheters removal was achieved through manual compression of the puncture sites (15 minutes for arterial access, 5 minutes for venous access).

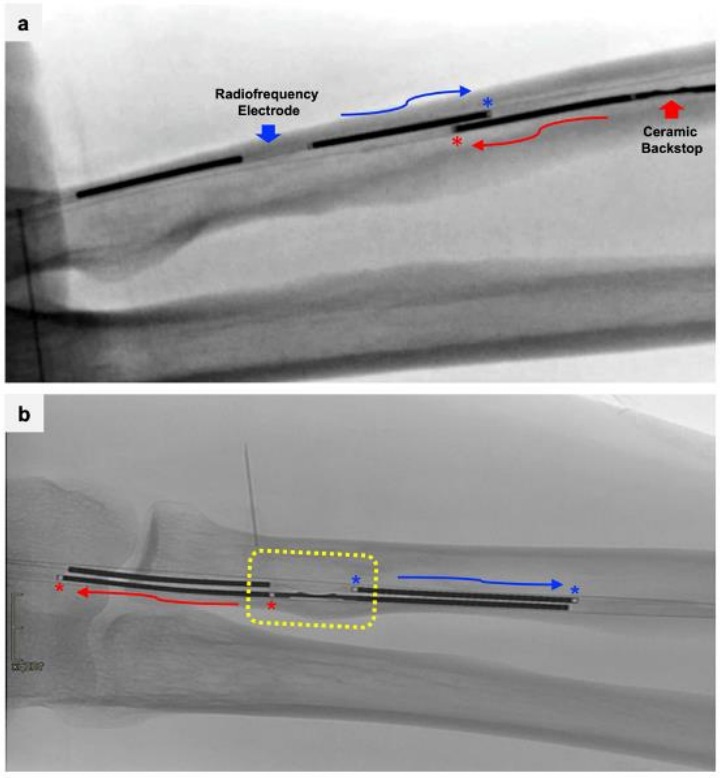

Figure 3 a) Catheters advancement to the target creation site under fluoroscopic guidance. In this case the "antiparallel approach" has been used (arterial access gained through the radial artery at the wrist, venous access obtained through the brachial vein from the upper arm). b) Fluoroscopic control of the correct alignment of the 2 magnets (yellow dashed rectangle). In both figures, the blue and red arrows indicate the venous and arterial catheter, while the blue and red asterisks indicate the venous and arterial rotational indicators, respectively.

Follow-up

The next phase involved short-term follow-up (24 hours, 7 days, 30 days) including blood flow rate measurement of the endoAVF by using color Doppler ultrasound, and medium- and long-term clinical/instrumental follow-up. Furthermore, timing of maturation and of venipuncture with 1 or 2 fistula needles were evaluated and recorded.

Results

The procedure was performed in 7 patients (6 male, 1 female) with ESKD. Main patients' clinical characteristics are reported in Table I. Mean age was 53.9±21.6 years. Mean BMI was 28.3±6. Regarding timing for referral to the nephrologist, 3 (43%) patients were early-referral and 4 (57%) late-referral. Only one early-referral patient met clinical indications to begin renal replacement

therapy before the creation of the endoAVF and thus a temporary vascular access (jugular CVC) was placed. All late-referral patients already had temporary or tunnelled CVC at the time of endoAVF creation.

The selected arm was non-dominant in 6 patients and dominant in 1 patient, due to the absence of anatomical eligibility criteria for the WavelinQ technique in the non-dominant arm. In only one case the AVF was performed on the side where the jugular CVC had previously been positioned; however, imaging confirmed the absence of central stenoses at the time of the procedure.

Table II shows the main anatomical characteristics recorded during pre-operative vascular mapping. Local anaesthesia was performed in 3 patients (43%), while brachial plexus anaesthesia was performed in 4 (57%). In 5 patients the approach was parallel (4 retrograde, 1 antegrade); in the remaining 2 patients an antiparallel approach was necessary (Table III). In all cases, the radial artery was chosen, and the anastomosis was created between the proximal radial artery and the lateral concomitant vein. The intraoperative arteriography confirmed the actual creation of the fistula in all patients. During the procedure, 4 patients (57%) underwent coil placement in the brachial vein, while intraoperative angioplasty was performed in 1 patient. No intra- or post-operative complications were observed (Table III). Mean duration of the procedure was 146 ± 35 minutes.

EndoAVF flows were monitored with color Doppler ultrasound over the brachial artery 24 hours, 7 days, 30 days, 6 and 12 months after the procedure (Table IV).

All patients met KDOQI maturation criteria within 1 month. EndoAVF venipuncture times were 53.6 ± 19 days (median 51) from the date of endoAVF creation (n = 5). In 2 early-referral patients on conservative therapy, the endoAVF was mature and adequate for venipuncture when the indication to start hemodialysis treatment was made. After the first month from the start of cannulation all endoAVF was deemed successfully used for hemodialysis (FUSH) [13].

The average follow-up time was 12.6 ± 6.2 months (median 12, range 5-21). Primary patency rates at 4, 6 and 18 months were 100%, 85.7%, and 71.4%, respectively. Cumulative patency rate during the entire follow-up period was 100%. During follow-up, 2 patients (29%) required corrective interventions with a re-intervention rate of 0.27 procedures per patient year (Table IV). In one case, due to the excessive flow dispersion in the deep circulation, embolization of the lateral brachial concomitant vein was needed approximately 15 months after endoAVF creation. The second patient underwent thrombectomy along with simultaneous percutaneous transluminal angioplasty (PTA) for venous side stenosis approximately 5 months after the endoAVF was performed (Table IV).

Age, years	53.9 ± 21.6
Male gender	6 (86%)
Smokers	2 (29%)
BMI	28.3±6
Diabetes mellitus	3 (43%)
Hypertension	5 (71%)
Patients on conservative medical therapy	2 (29%)
Patients already undergoing hemodialysis	5 (71%)
Early-referral	3 (43%)
Late-referral	4 (57%)
Previous vascular access	
– Temporary contralateral trans-jugular CVC	2 (29%)
– Long-term ipsilateral trans-jugular CVC	1 (14%)
– Long-term contralateral trans-jugular CVC	1 (14%)
– Femoral CVC	1 (14%)
– No previous vascular access	2 (29%)

Table I. Main clinical characteristics of the patients (n=7). Continuous variables expressed as mean±SD; categorical variables expressed as n (%). CVC: central venous catheter.

PATIENT ID	1		2		3		4		5		6		7	
Cephalic vein (mm) Diameter/depth	D	d	D	d	D	d	D	d	D	d	D	d	D	d
· Proximal	<2.5	n.a.	3.4	2.4	<2.5	n.a.	<2.5	n.a.	3	4.8	2.5	6	<2.5	n.a.
· Middle	<2.5	n.a.	3.6	2.3	<2.5	n.a.	<2.5	n.a.	2.7	2.7	2.5	6	<2.5	n.a.
· Distal	<2.5	n.a.	3.8	2.2	<2.5	n.a.	3.5	3.5	3.2	2.9	2.5	1.9	<2.5	n.a.
Basilic vein (mm) Diameter/depth	D	d	D	d	D	d	D	d	D	d	D	d	D	d
· Proximal	6	6.7	7	14	2.5	6	6	11	5.2	1.5	2.5	6	4.1	6
· Middle	5.8	5.9	7	10	3.2	7.7	5.5	2.8	2.9	6	2.5	6	4	6
· Distal	6.7	4.1	5	11	3	2	4	3.8	3	3.2	3.2	4.1	4	4
Brachial artery														
· Diameter (mm)	3.7		5		5.3		5.8		4.7		5		5	
· Bifurcation (above/below elbow)	below		below		below		below		below		below		below	
· Triphasic flow	Yes		Yes		Yes		Yes		Yes		Yes		Yes	
Perforating vein														
Patency	Yes		Yes		Yes		Yes		Yes		Yes		Yes	
Diameter (mm)	2.8		2.4		2.9		3.3		3.5		3.6		3.8	
Connection	L.R.V.		L.R.V./M.R.V.		L.R.V.		L.R.V.		L.R.V.		L.R.V./M.R.V.		L.R.V./L.U.V.	

Table II. Anatomical characteristics resulting from pre-operative vascular mapping. L.R.V.: Lateral radial vein; M.R.V.: Medial radial vein; L.U.V.: Lateral ulnar vein. n.a.: not applicable (depth not assessed in the case of inadequate vessel diameter).

PATIENT ID		1	2	3	4	5	6	7
Devices access sites								
Radial artery diameter (mm)	wrist	2.4	2.6	3.2	2.8	2.2	2	2.5
Lateral radial vein diameter (mm)		<2	<2	<2	<2	2.2	2.1	2
Medial radial vein diameter (mm)		<2	<2	<2	<2	2.2	2	<2
Brachial artery diameter (mm)		3.7	5	5.3	5.8	4.7	5	5
Lateral brachial vein diameter (mm)		3.7	3.5	<2	4.8	2.5	5	5
Medial brachial vein diameter (mm)		2	2.2	3.4	4.8	<2	<2	2.5
Creation site								
Radial artery diameter (mm)		2.5	3	3.5	2.2	2.2	2.9	3.2
Lateral radial vein diameter (mm)		2.5	3.1	2.4	3.5	2.6	2.3	3
Medial radial vein diameter (mm)		4.8	<2	<2	3.6	<2	2.9	2
Intraoperative variables								
Parallel/**A**ntiparallel approach		A	A	P	P	P	P	P
Intraoperative embolization		No	No	Yes	No	Yes	Yes	Yes
PTA		No	Yes	No	No	No	No	No
Complications		No	No	No	No	No	No	No

Table III. Anatomical characteristics of endoAVF devices access sites, creation site, and intraoperative variables. PTA: percutaneous transluminal angioplasty

Blood flow rates (ml/min) measured at brachial artery								
PATIENT ID	1	2	3	4	5	6	7	N=7
24 hours	550	600	800	750	360	450	450	566±163
7 days	1000	750	950	900	1200	600	450	836±254
30 days	1100	850	1000	900	1200	650	600	900±222
6 months	1000	700	1000	700	1100	1000	800	900±163
12 months	1200	700	1000	800	1100	1100	n.a.	983±194
Need for corrective interventions and timing from endoAVF creation								
PATIENT ID		1	2	3	4	5	6	7
Procedure		No	Yes	Yes	No	No	No	No
Coiling		–	15 months	–	–	–	–	–
PTA		–	–	5 months	–	–	–	–
Thrombectomy		–	–	5 months	–	–	–	–

Table IV. Blood flow rates and need for corrective interventions during the follow-up period. Data expressed as mean ± SD. PTA: percutaneous transluminal angioplasty. n.a.: not applicable

Discussion

The arteriovenous fistula represents the vascular access of first choice for ESKD patients requiring hemodialysis [1, 2]. In recent years, two different techniques have been proposed to create a fistula in the proximal forearm percutaneously without the need for a surgical incision [3, 4]. Among these non-surgical AVF creation options, the WavelinQ EndoAVF System is indicated to perform an arteriovenous connection between the radial artery and its concomitant vein or the ulnar artery and its concomitant vein in patients with well-defined anatomical characteristics. From the anastomosis the blood flows through the perforating vein into the superficial circulation, thus allowing the arterialization of cephalic and/or basilic vein.

Our preliminary experience allows to confirm the efficacy and safety of the endovascular procedure by using the WavelinQ System. Indeed, in the first 7 patients who underwent the procedure of endoAVF creation at our center the technical success was 100%. During the observation period (>12 months in 4 cases and >5 months in the remaining patients) primary and cumulative patency rates were 71.4% and 100%, respectively. Moreover, no peri-operative complications such as vascular lesions or arm ischemia occurred. Although obtained in a limited sample of patients, these findings agree with literature data [8, 11, 14, 15]. For example, in a study of pooled data from three prospective, multicenter, single-arm trials procedural success was achieved in 116 patients (96.7%), while the primary and secondary patency rates were 71.9% and 87.8% at 6 months, respectively [8]. More recently, in a prospective, single-center study including a total of 20 patients, technical success was 100% in absence of serious adverse events; at 6-month follow-up, the primary and cumulative patency rates were 65% and 75%, respectively [11]. Moreover, Inston et al, comparing a single-center series of WavelinQ endoAVF with a matched series of surgically created radiocephalic AVF, reported a significantly greater mean primary patency in the endoAVF group (362 ± 240 vs 235 ± 210 days, $p<0.05$) [14].

Pre-operative vessel mapping is an important step in identifying patients who can successfully undergo an endoAVF procedure. Thus, an accurate ultrasound examination plays a key role to assess the presence of the specific anatomical characteristics required to create a well-functioning fistula by using this system. For this purpose, we have implemented a well-trained specialized team including nephrologist and interventional radiologist to take advantage of their specific skills in the crucial phase of patient's selection. Moreover, it is well recognized that this collaboration is also essential to achieve and maintain a functional AVF. Starting from this assumption, at our hospital,

during the intraoperative phase nephrologists and interventional radiologists together evaluate the need for further intraprocedural interventions aimed at diverting greater blood flow towards the superficial veins. Thus, in our experience, 5 out of 7 patients underwent coil placement in the brachial vein or intraoperative angioplasty. These procedures facilitated the maturation of the endoAVF and possibly contributed to limit the need for subsequent re-interventions. In our patients, procedures aimed at maintaining the patency of the access and strengthening the inflow and outflow, were necessary in only 2 cases. In this regard, the need for subsequent procedures to facilitate the maturation of the AVF, intended as PTA or coiling on deep circulation veins, has been reported in few cases also by other authors. Indeed, data published so far seems to show that, compared to the surgical approach, the WavelinQ technique requires fewer re-interventions, thus compensating potential higher initial costs [16–18]. In particular, in a propensity score study matching 60 endoAVF with 60 surgical AVF patients, Yang et al found that the endoAVF group required significantly fewer post-creation procedures with consequently lower mean costs within the first year [16]. Furthermore, a cost-effectiveness and budget impact analysis, conducted in hemodialysis patients from the prospective of the Italian Healthcare Service, suggested that endoAVF could be a cost-saving strategy compared to surgical AVF creation [18].

Post-procedure follow-up is an essential component in access management. Indeed, regular follow-up makes it possible to verify that the endoAVF is properly working to deliver adequate dialysis and to timely identify the need for corrective measures, thus allowing to significantly increase the AVF lifespan. The follow-up phase involves careful routine monitoring even in the period following the start of endoAVF venipuncture. The role of the nephrologist become central when maturation is completed and endoAVF can begin to be used. To minimize the failure risk of the first venipunctures, the right approach is to identify possible sites for correctly positioning the needles through ultrasound evaluation. A good practice is to assign an experienced operator (physician or nurse) to perform the first cannulations. In our experience, within the first 4 weeks from the start of venipuncture, all endoAVF were considered successfully used for dialysis, that is, they were used with two-needle cannulation for two-thirds or more of all dialysis runs for 1 month, delivering the prescribed dialysis within the prescribed time frame [13]. In our opinion, endoAVF appears to offer an interesting opportunity among vascular access creation options. The use of the deep circulation expands the anatomical options for the creation of AVF, preserves the patient’s venous circulation without precluding any subsequent endovascular or surgical approach [14]. It should also be considered that the anastomosis is performed without dissection and traumatism of the vessels and surrounding tissues, with a possible lower predisposition to a subsequent development of aneurysms and venous stenosis [15, 19]; the former are often a cause of discomfort for patients. Moreover, the minimally invasive technique does not produce surgical scarring that could disfigure the arm. In this regard, an aspect that should not be overlooked is patient satisfaction [20]. In fact, in the examined cases the endoAVF had minimal aesthetic impact and no patient complained of symptoms (e.g., pain, paresthesia) or functional limitation of the affected arm.

Conclusion

This study, although it includes a limited number of patients and it is characterized by a relatively short follow-up period, confirms that the WavelinQ technique, if performed by operators well-trained in performing and monitoring of endoAVF, could be considered safe and effective. This innovative and constantly evolving technique adds a further option in the choice of optimal vascular access for the hemodialysis patient with the aim of ensuring ever greater personalization of therapeutic choices.

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