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Endovascular arteriovenous fistula creation

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Abstract-- Functioning vascular access is an essential element for life-saving hemodialysis therapy. A surgically-created arteriovenous fistula has been considered the best option for many years. Recently, two manufacturers developed systems for percutaneous/endovascular creation of an arteriovenous fistula. Shahverdyan et al. looked back at the records of 100 people who had 4-Fr WavelinQ and Ellipsys endoAVF implants. During the index operation, the WavelinQ cohort had brachial vein ablation, and the Ellipsys group had balloon angioplasty of the junction. There were no big changes between the two groups at the start (6). This study showed that compared to WavelinQ (19), Ellipsys has higher total patency rates but the same maturity rates and dialysis rates.

Keywords---Endovascular Arteriovenous, EndoAVF, Fistula Creation.

Anatomy

The majority of hemodialysis surgical fistulas are made in the upper extremities, namely within the radiocephalic, brachiocephalic, and brachio-basilic systems. whichever is Endoarterial venous fenestration (EndoAVF), the device used to create the fistula can use the radial artery and vein, the ulna artery and vein, or the radial artery and a venous perforator in the distal upper arm. (1).

Perforator Veins

Both the superficial venous system and the deeper venous system help to drain blood from the upper limbs. The main parts of the peripheral venous system are the basilic vein and the cephalic vein, which are located in the wrist and upper arm. The forearm's radial, ulnar, and interosseous veins connect and flow into the upper arm's brachial vein as part of the body's deep venous system. A perforator vein in the distal forearm (beyond the antecubital fossa) connects both of these systems. Both the WavelinQ and the Ellipsys devices need a perforator vein as the pathway for arterialized blood from the veins to go from the deep venous system to the superficial venous system. No veins accessible for dialysis cannulation would exist lacking this superficialization of flow (1, 2).

Fistula Sites

Fistulas between the radial artery and vein or the ulnar artery and vein may be made with the WavelinQ technology. Because of their closeness to one another and the ease with which they may be reached percutaneously, the radial and ulnar arteries and veins are often targeted. Specifically, the radial artery closely parallels the radial vein, while the ulnar artery parallels the ulnar vein. Because of their close proximity, the magnetic components utilized to create the fistula may be easily aligned with the WavelinQ device. Their position in the upper extremity's distal third also protects the proximal vessels in case more fistula attempts are needed in the future (3).

The Ellipsys system connects the proximal radial artery (PRA) to the deep connecting vein (DCV) at the end of the upper limb. Due to how close the PRA and DCV are to each other, they can both be pierced with a single needle and fistulized with direct radiofrequency (RF) radiation. This is all done with the Ellipsys system. (4).

Pre-procedure Considerations

Patient Selection

Individuals who prefer not to have surgery or who have contraindications to it might benefit greatly from endoAVF because of how less invasive it is compared to surgical AVF (sAVF) development. Individuals for whom a radiocephalic (Breccia-Cimino) fistula is medically or surgically impossible may also benefit from endoAVF. If a patient has substantial arterial or venous flow restriction, endoAVF formation should not be attempted. Individuals with flow-limiting transmural calcification of the arterial walls or thrombosed cephalic or basilic veins ought not to undergo endoAVF formation (1).

Timing

If a fistula is made surgically or endovascularly, it may take several weeks to months for the fistula to mature and become useable. If hemodialysis is anticipated in advance, the fistula may develop in time for use. Facilitating timely fistula development and reducing the need for CVC insertion (5) may be achieved via provider coordination.

Vessel Mapping

Patients who could benefit from endoAVF development should have their vessels evaluated for architecture and patency. Eligibility for endoAVF varies per device, although the WavelinQ and Ellipsys systems have many of the same requirements. To be eligible for treatment with the WavelinQ system, patients must have a patent perforator with a diameter of at least 2 mm, a healthy brachial artery and vein, a healthy ulnar artery and vein, or a healthy radial artery and vein. Target vessels

must also be separated by no more than 2 mm. The WavelinQ system (3) may be inserted via a variety of access locations, including the brachial artery/vein, ulnar artery/vein, and radial artery/vein.

If the patient's PRA and perforator venous sizes are smaller than 2 mm and 1.5 mm, accordingly, the Ellipsys system may be used to treat them. It is necessary for the vessels to be close together for successful fistula formation (6) because of the mechanics of the Ellipsys system (i.e., single, direct puncture of the nearby target vessels).

Technique

1. Ellipsys

Equipment/Procedure

Utilizing pressure and temperature resistance, the Ellipsys Vascular System (Avenu Medical, Inc., San Juan Capistrano, California) may generate a per-cutaneous AVF for hemodialysis admission. The proximal radial artery (PRA) and a large connecting vein in the proximal forearm (7) are joined together using this thermally resistant anastomosis device (TRAD).

The Ellipsys Vascular system provides the advantages of a PRA-AVF by constructing the anastomosis by an endovascular technique, therefore eliminating the risks associated with surgical scarring that may induce stenosis and restrict the cannulation zone. By preserving both median superficial veins, a Y-shaped fistula is formed, potentially increasing the fistula's length and providing more cannulation site choices. Lower pressure has also been hypothesized to reduce the incidence of aneurysms and the outflow turbulence and shear stress on the vessel wall (4, 8).

This non-hospitalized procedure often makes use of nerve blocks or local anesthesia either alongside or without light sedation. Ultrasound is used to guide the whole operation, which means no radiation is ever exposed to the patient. Retrograde entry into the median cubital or brachial vein is accomplished using a typical micropuncture needle and wire, as reported by Hull et al. The ultrasonography is used to guide the intravenous advancement of the access needle until it is close to the PRA. A needle was used to puncture the PRA, and ultrasound shows that the wire was advanced distal in the radial arteries. A Six Fr Glidesheath Slender sheath (Terumo Medical Corp, Somerset, New Jersey) is placed after the artery has been found. By doing so, the TRAD may be advanced into the sheath in an "open" posture, with its apex in the PRA and its base in the vein being accessed. After the Ellipsys catheter has been inserted into the PRA, the sheath is withdrawn and traction is given to the device's tip to bring it into contact with the PRA's inner wall. The anastomosis is then fused and severed by closing the device and activating it. Hemostasis may be achieved by maintaining physical pressure on the anastomosis after the device has been withdrawn through the sheath. In the event of an emergency, balloon dilation may be performed immediately on this tissue-fused anastomosis. During the device's early clinical trials, instantaneous balloon dilation was employed on a case-by-case basis to modify and reroute blood flow into the hemodialysis machine's output vein (9).

After employing TRAD, Mallios et al. (4) experimentally performed angioplasty at nominal pressure using a 5 mm balloon to find that this reduced the requirement for further angioplasty to increase access flow.

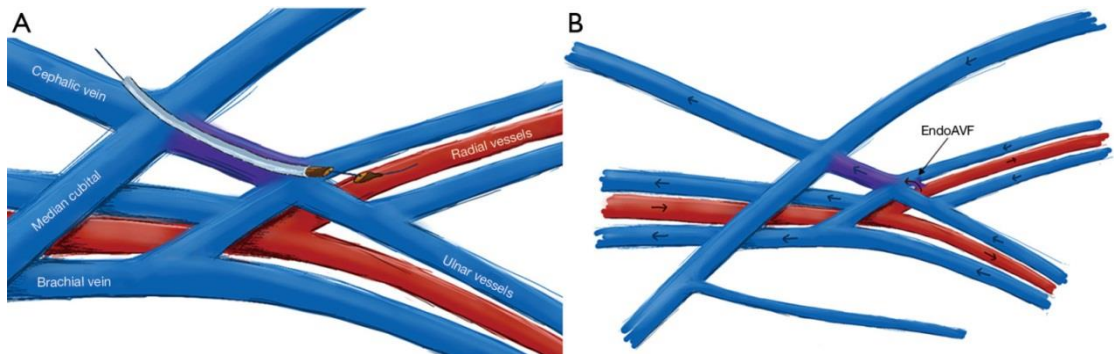


Figure (1): Plan for making an endoAVF in Ellipsys. Normal configuration of an Ellipsys system (A). After inserting the venous catheter via the perforator, it is guided into the nearby radial artery. Keep in mind how the catheter is inserted, with its tip in the arterial canal and its base in the venous lumen. Flow from the radial artery is redirected into the perforator vein (the lilac vein) thanks to an endoarterial venous fistula (EndoAVF) formed between the radial artery and the neighboring vein (B). endoAVF, or endovascular arteriovenous shunt formation. endoAVF, or arteriovenous fistula formation by endovascular means (7).

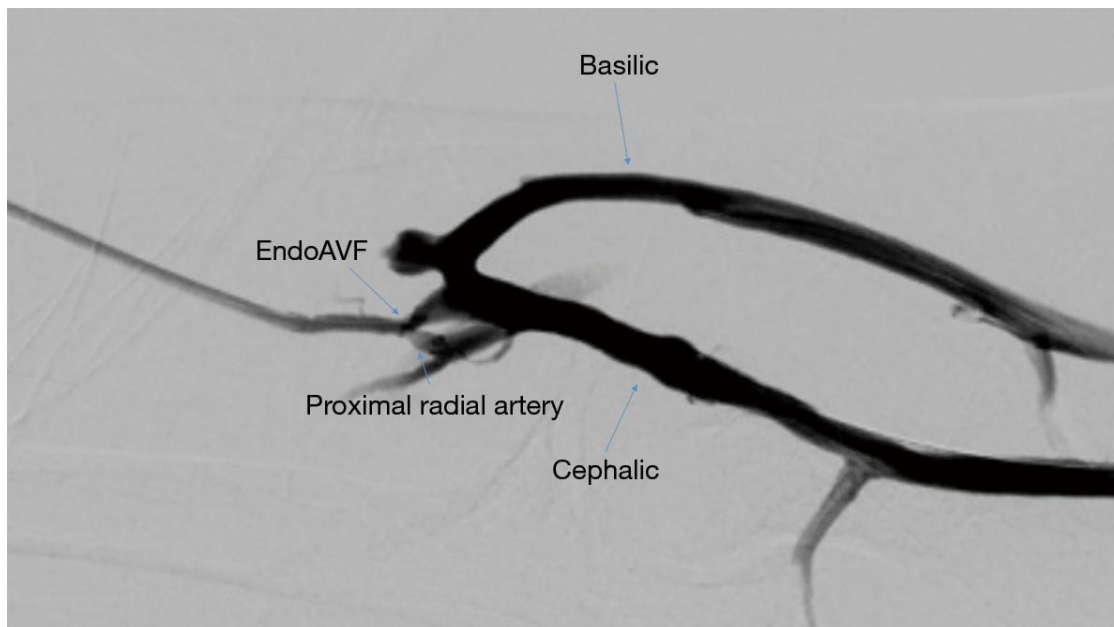


Figure (2): The vascular structure of Ellipsys after the Flood. Specifically, the proximal radial artery is the connecting point. (7).

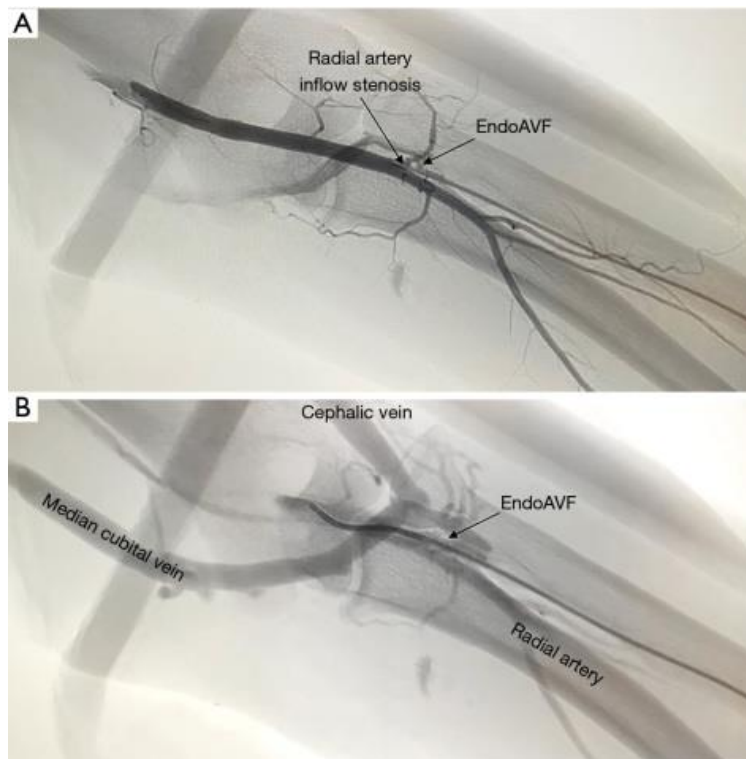


Figure (3): Ellipsys endoAVF pictures before and after angioplasty for inflow stenosis. Proximal radial artery inflow stenosis was shown on an angiography before angioplasty (A), and after angioplasty with a 4 mm 20 mm balloon (B). Proximal radial artery and endoAVF flow improvement during inter-intervals (7).

Indications/Contraindications

The Ellipsys system requires a vascular diameter of at least 2 mm and a distance of less than 1.5 mm between the PRA and deep communicating vein. If the target patient's artery and vein are more than 1.5 mm apart, the device cannot be used. (10).

2. WavelinQ

Equipment/Procedure

After being inserted into a closely-applied artery and vein in the upper forearm, typically the ulnar artery and vein, the WavelinQ (formerly EverlinQ) Endo AVF System (Becton Dickinson, Franklin Lakes, NJ, USA) is a dual-catheter structure that uses powerful rare-earth magnets for both catheters to establish and keep a the right position. This system is manufactured in the United States. Activating a radiofrequency (RF) electrode on the venous catheter close to a ceramic backstop on the arterial catheter creates a from side to side AVF (11), which causes the vessel walls to heat up and evaporate.

It was necessary to have both a 7 Fr venous sheath and a 6 Fr arterial sheath in order to implant the 6 Fr catheter system of the first generation. Access sites for catheters may be situated in the upper arm or the wrist (7), and arterial and venous

access can be organized in a manner that is either parallel to or anti-parallel to one another.

Before beginning the procedure, the patient should undergo ultrasound Doppler vascular mapping to determine whether or not the patient's arteries and veins are sufficiently broad to produce a fistula in the forearm. Patients were selected for clinical trials based on whether or not they had target artery and vein diameters of 2 millimeters and a superficial venous architecture that was suitable for the creation of a SAVF, as recommended by KDOQI. An Allen test is the best way to determine whether or not your radial and ulnar arteries are dominant, as well as whether or not they are patent (11, 12).

The procedure is often performed with the patient under the influence of a local anesthetic and some level of light sedation. Patients get an intravenous dose of heparin ranging from one thousand to five thousand units, depending on the operator and the design of the research. Only then will the magnets be able to do their job. After the channel has been formed by an RF pulse that lasts just 0.7 seconds, the blocking mechanisms may be turned off. After the AVF has been successfully constructed, an angiography is performed by inserting a catheter into the artery that was utilized for access. The central deep brachial vein is often embolized (with coils or a vascular plug) in order to further stimulate flow from the deeply veined system via the perforator vein into the region of interest superficial access veins (7). This is done in order to further stimulate flow from the deep venous system.

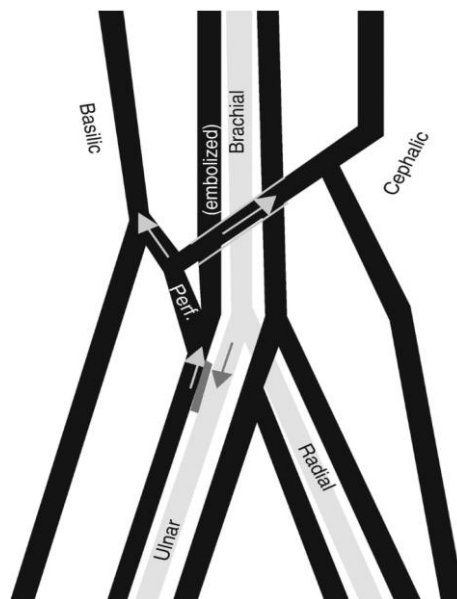


Figure (4): The anatomical connection between the fistula, the arteries (gray), and the veins (black) is shown in this diagram. Flow directions are shown by arrows. To redirect blood flow to the more advantageous perforator, cephalic, and/or basilic veins, embolization of a competing brachial vein is a common procedure. **(7)**.

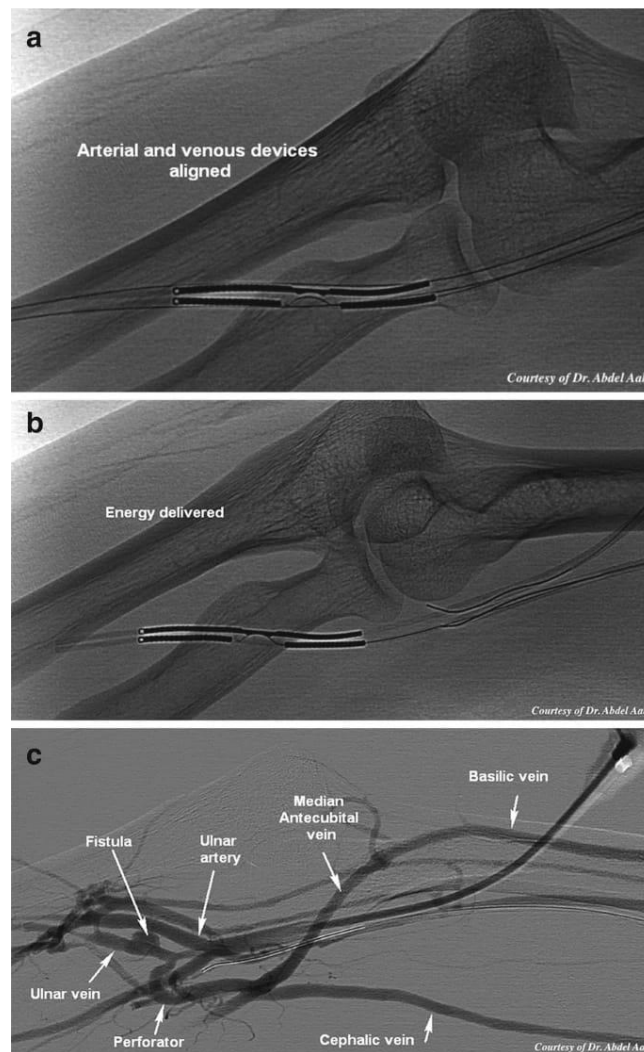


Figure (5): Before activating the radiofrequency pulse, (a) make sure the arterial and venous catheters are aligned with the deployed electrode. (b) After a pulse is activated, the spring-loaded electrode completely abuts the ceramic endplate, indicating that a fistula has been formed. (c) The fistula and outflow channels are seen on a brachial artery angiography after completion. **(7)**.

Indications/Contraindications

The construction of an endovascular AVF (3) might be of assistance to patients who do not need dialysis (chronic kidney disease (CKD) stages 4 or 5) as well as those who do require dialysis but require hemodialysis access, regardless of whether or not a fistula has failed.

Patients were not permitted to take part in recent clinical studies if they had any of the following conditions: non-amenable vascular anatomy (defined as having a central venous narrowing of more than fifty percent or additional identified as upper extremity occlusions/stenosis), cardiac failure, hemorrhaging diathesis or hyper-

coagulable state, suppression of the immune system, acute infection, serious congestive cardiac failure (ejection fraction of twenty percent), or a referred to allergies to contrast dye that.

In recent clinical studies, patients were not allowed to take part if they had non-amenable vascular anatomy (those who are with central venous narrowing > fifty percent or other referred to upper extremity occlusions/stenosis), heart failure, hemorrhaging diathesis or hypercoagulable state, immune suppression, acute infection, serious congestive heart failure (ejection fraction twenty percent), or a referred to allergy to contrast dye that could not be treated with premedication (13).

Outcomes

In contrast to surgery, endovascular methods can be used to create arteriovenous fistulae without the need for an operating theatre. Procedures are done under local anaesthesia and/or aware sleep, and small cuts are made so that the body can heal more quickly. Depending on the subject, other steps might need to be taken (14).

There is evidence that endovascular arteriovenous fistulae creation is just as good as surgical methods and doesn't stop most people from getting arteriovenous fistulae created through surgery. Endovascular procedures have been shown to have a high rate of technical success and a high rate of patency afterwards (15, 16). Because endovascular methods cause less surgery stress, which is a risk factor for neointimal hyperplasia, they may cut down on the need for re-intervention (17). At the moment, more comparison studies and longer-term data are needed to fully evaluate how useful this new method is for treating people who need dialysis access (18).

Comparison of EndoAVF systems

There has only been one study done to compare the two endoAVF methods in the past. Shahverdyan et al. looked back at the records of 100 people who had 4-Fr WavelinQ and Ellipsys endoAVF implants. During the index operation, the WavelinQ cohort had brachial vein ablation, and the Ellipsys group had balloon angioplasty of the junction. There were no big changes between the two groups at the start (6).

There were 34 WavelinQ endoAVF and 65 Ellipsys endoAVF made. WavelinQ's cohort had a 97% success rate, and Ellipsys's group had a 100% success rate. 8.5% of WavelinQ patients and 1.5% of Ellipsys patients experienced major side effects during follow-up. At 12 months, the total patency rates for WavelinQ and Ellipsys endoAVF were 60% and 82%, respectively (HR 0.42, 95% CI: 0.19–0.97). The maturation rates (brachial artery >500 mL/min and target (cephalic and/or basilic) vein >5 mm) were 54% and 68%, respectively. WavelinQ and Ellipsys endoAVF had secondary intervention rates of 0.46 and 0.96 per patient-years, respectively, but the writers did not say if that was a statistically significant difference. This study showed that compared to WavelinQ (19), Ellipsys has higher total patency rates but the same maturity rates and dialysis rates.

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