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Feasibility of creation of an endovascular arteriovenous fistula in patients undergoing preoperative vascular mapping

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Key Points:
* Among patients who are eligible for a surgical fistula, 63% were suitable for endoAVF.
* Older patients were less likely to have a vascular anatomy suitable for an endoAVF.
* Patients with a vascular anatomy suitable for an endoAVF were similar in sex, race, DM, HTN, CAD, and peripheral artery disease.

Abstract:
Background: The first endovascular arteriovenous fistula (endoAVF) device (WavelinQ), a novel percutaneous technique of AVF creation, was approved by the Food and Drug Administration in 2018, and has been placed in a small number of U.S. hemodialysis patients. It is unknown how often patients with advanced chronic kidney disease have vascular anatomy suitable for WavelinQ creation. The goal of the present study was to determine the proportion of patients with vascular anatomy suitable for WavelinQ creation, and to assess patient characteristics associated with such suitability. Methods: All patients referred for vascular access placement at a large academic medical center underwent standardized preoperative sonographic vascular mapping to assess suitability for an AVF. During a two-year period (March 2019 to March 2021), we assessed the suitability of the vessels for creation of a WavelinQ. We then compared the demographic characteristics, comorbidities, and vascular mapping measurements between patients who were or were not suitable for a WavelinQ. Results: During the study period 437 patients underwent vessel mapping. Of these, 51% of patients were eligible for a surgical AVF and 32% were eligible for a WavelinQ AVF. 63% of those suitable for a surgical AVF were also suitable for a WavelinQ AVF. Patients with a vascular anatomy suitable for a WavelinQ were younger (age 55{plus minus}15 vs 60{plus minus}14 years, p=0.01), but similar in sex, race, diabetes, hypertension, coronary artery disease, and peripheral artery disease. Conclusions: Among patients with chronic kidney disease with vascular anatomy suitable for a surgical AVF, 63% are also suitable for an WavelinQ endoAVF. Older patients are less frequently suitable for a WavelinQ.

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Author Contributions: Alan Al-Balas: Conceptualization; Data curation; Formal analysis; Methodology; Writing - original draft; Writing - review and editing Rakesh Varma: Resources; Supervision; Writing - review and editing Kedar Sharbidre: Resources; Validation; Writing - review and editing Hassan Al-Balas: Formal analysis; Project administration; Supervision; Writing - review and editing Ammar Almehmi: Project administration; Supervision; Writing - review and editing Ahmed Abdel Aal: Conceptualization; Data curation; Methodology; Writing - review and editing Michelle Robbin: Validation; Writing - review and editing Michael Allon: Conceptualization; Supervision; Validation; Visualization; Writing - review and editing

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Feasibility of creation of an endovascular arteriovenous fistula in patients undergoing preoperative vascular mapping

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Results: During the study period 437 patients underwent vessel mapping. Of these, 51% of patients were eligible for a surgical AVF and 32% were eligible for a WaveLinq AVF. 63% of those suitable for a surgical AVF were also suitable for a WaveLinQ AVF. Patients with a vascular anatomy suitable for a WavelinQ were younger (age 55±15 vs 60±14 years, p=0.01),
but similar in sex, race, diabetes, hypertension, coronary artery disease, and peripheral artery disease.

**Conclusions:** Among patients with chronic kidney disease with vascular anatomy suitable for a surgical AVF, 63% are also suitable for an WavelinQ endoAVF. Older patients are less frequently suitable for a WavelinQ.

**Introduction**

An arteriovenous fistula (AVF), the preferred type of vascular access for hemodialysis, is created by a direct surgical anastomosis between a peripheral artery and vein. To be eligible for a surgically created AVF, several preoperative vascular characteristics are used by many centers: an arterial diameter $\geq 2.0$ mm, a venous diameter $\geq 2.5$ mm, and absence of stenosis or thrombosis of the feeding artery and candidate draining vein (1-3). A preoperative vessel mapping is frequently obtained prior to AVF creation to ascertain whether these criteria are fulfilled. Specifically, patients may not be eligible for an AVF if the intended vein diameter is too small or if the draining vein has been damaged by prior cannulation.

Even when an AVF is created in a patient meeting these vascular parameters, it may fail to mature adequately for successful dialysis. One common cause of AVF non-maturation is the development of a flow-limiting juxta-anastomotic stenosis(4, 5). The stenosis is, in part, a consequence of aggressive neointimal hyperplasia, which may arise from surgical vascular injury or abnormal shear stress near the AVF anastomosis (6). Surgically created AVFs typically have a 30 to $45^\circ$ angle at the anastomosis. Computational fluid dynamics suggest that an anastomotic angle $<30^\circ$ improves the flow hemodynamics, and pilot clinical data demonstrated that a smaller surgical anastomotic angle reduced juxta-anastomotic stenosis (7, 8). As a consequence, there has been great interest in novel AVF technologies that limit vascular injury and improve flow
dynamics and may theoretically lead to maturation rates superior to those of surgically created AVFs.

Endovascular AVF (“endoAVF”) is a novel percutaneous technique of AVF creation, with several devices recently approved for use in the U.S. by the Food and Drug Administration (FDA) (9, 10). One of these devices, the WavelinQ, is used at our medical center. In contrast to the surgical technique, the WavelinQ potentially minimizes vascular injury at the time of AVF creation by using a minimally invasive technique. Moreover, by creating a side-to-side anastomosis between the artery and vein, it improves the flow hemodynamics near the anastomosis. Finally, it provides a dual outflow from the artery, enabling maturation of both the cephalic and basilic veins. These three features of a WavelinQ provide a potential rationale for its superior maturation, as compared to a surgical AVF.

Creation of the WavelinQ requires two additional anatomic features beyond those required for surgical AVF creation. First, there must be an ulnar artery and ulnar vein of adequate diameter in close proximity to each other (within 2 mm). Second, there must be a patent and an adequately sized perforator vein allowing drainage from the deep ulnar vein into the superficial veins in the upper arm. If the ulnar artery or vein are too small, an alternative approach entails creating an anastomosis between the radial artery and vein in the proximal forearm.

Publications on the WavelinQ device to date have consisted of small series and have not systematically determined how often patients with advanced chronic kidney disease have the anatomy suitable for AVF creation(11-13).(9, 10, 14) The current study obtained routine preoperative vascular mapping in all patients referred for vascular access surgery at a single large dialysis center over a two-year period, determined the proportion of patients who were suitable for the WavelinQ, and compared clinical features between patients with or without anatomy
suitable for a WavelinQ. The importance of the present study is to assess the proportion of patients suitable for a WavelinQ, and to identify patient characteristics that may limit the use of this type of endoAVF. It can also identify the type of patients in whom a surgically created AVF is preferred.

**Methods**

*Preoperative vascular mapping protocol for surgical AVFs*

All patients referred for vascular access placement at the University of Alabama at Birmingham (UAB) first underwent a standardized preoperative sonographic vascular mapping. The standard preoperative ultrasound for surgically created AVFs assesses the diameter of the superficial veins (cephalic and basilic) and the largest brachial vein, as well as assessing the potential inflow segments of the brachial and radial arteries. To be eligible for a surgically created AVF, our institutional protocol required an arterial diameter $\geq 2.0$ mm, a venous diameter $\geq 2.5$ mm, and exclusion of stenosis or thrombosis of the feeding artery and candidate draining vein (1-3).

All ultrasound measurements were performed by experienced sonographers in an American College of Radiology Accredited ultrasound department using a tourniquet. The non-dominant upper extremity was first evaluated. If no criteria met for AVF was found, then the other extremity was evaluated. Duplex ultrasound mapping of the upper extremity with tourniquet included the basilic and cephalic vein diameters and depths at prescribed locations in the cranial and mid upper arm, antecubital area, mid forearm and wrist. The presence of high brachial artery takeoff was also reported, if present (15).
Anatomic prerequisites for an endoAVF

One of the endoAVF technologies, the WavelinQ EndoAVF (WQ) system (Bard Peripheral Vascular, Tempe, AZ) uses a percutaneous technique to create an anastomosis between the ulnar or radial artery and its adjacent vein in the proximal forearm(16). Briefly, arterial and deep venous magnetic catheters are placed under fluoroscopy. The magnets are then activated in both catheters to align the artery and vein. A spring-loaded radiofrequency electrode is released from the venous catheter and energized for 2 seconds, creating a channel between the vein and the artery (Figure 1). Thus, preoperative mapping for an endoAVF requires all the vascular measurements obtained for a surgically created AVFs, as well as two additional measurements of the ulnar artery, ulnar vein, and perforating vein. First, there must be an ulnar artery and ulnar vein of adequate diameter in close proximity to each other (within 2 mm). Second, there must be an adequately sized (>2 mm) patent perforator vein allowing drainage from the deep ulnar vein into the superficial venous veins in the upper arm. If the ulnar artery or vein are too small, an alternative approach entails creating an anastomosis between the radial artery and vein in the proximal forearm (Figure 2).

Data collection

Two full-time access coordinators scheduled all vascular access procedures performed by surgeons, radiologists, or nephrologists, and maintained a prospective, computerized database of these procedures (17). The data collection included all patients undergoing preoperative vascular mapping during a two-year period. The UAB Institutional Review Board approved review of the electronic medical records for research and provided a waiver from obtaining informed consent. The focus of this study was to quantify the proportion of patients who were anatomically eligible
for a WavelinQ. In addition, each patient’s electronic medical record was reviewed to extract demographic and clinical information.

Statistical Analysis

Initially, we ascertained the proportion of patients with a preoperative vascular anatomy suitable for a surgically created AVF who were also suitable for a WavelinQ. We then compared the demographic, clinical and vascular properties of patients who were suitable for a WavelinQ to those who were not suitable. Baseline features of the patients were compared by Chi-square test for categorical variables and by Student t-tests or nonparametric statistics for continuous variables. P <0.05 was considered statistically significant.

Results

We identified 437 patients who underwent preoperative vascular mapping from March 2019 to March 2021 at UAB. Of these, we excluded 214 patients whose anatomy precluded creation of a surgical AVF. The remaining 223 patients were considered eligible for a surgical AVF (and 95% of them were receiving their first access in that extremity). Of this cohort, 140 (or 63%) were also suitable for endoAVF creation using the WQ system. In other words, of all 437 patients referred for a vascular access, 140 (or 32%) were suitable for WavelinQ. The proportion of patients eligible for a surgical AVF who were also suitable for a WavelinQ was very similar for the subset of patients who were ESKD (115 of 182, or 63%) and pre-ESKD (25 of 41, or 61%). Among the 83 patients who were not suitable for a WavelinQ, 33 were due to the absence of a perforator vein, 29 because the perforator vein was smaller than the minimal threshold, and 21 because the ulnar and radial artery or vein were below the desired threshold (Figure 3).
As compared to patients unsuitable for a surgical AVF, those who were suitable for a surgical AVF were less likely to be Black, but did not differ in other demographic or clinical characteristics. Among the subset of patients suitable for a surgical AVF, those suitable for a WavelinQ were younger than those not suitable for this access type (Table 1). The two groups were similar in terms of diabetes, hypertension, cardiovascular comorbidities, as well as laterality of the arm and presence of high radial artery takeoff. Most of patients (80%) had already initiated hemodialysis prior to undergoing preoperative vascular mapping.

Since WavelinQ suitability differed by patient age, we subsequently compared the individual characteristics of the deep venous system between older (age >60 years) and younger (age < 60 yr) patients (Table 2). Absence of a perforator vein was similar in both age groups, but older patients were more likely to have a perforator vein smaller than the 2 mm threshold (38% vs 20%, p=0.004). Among those patients with a perforator vein diameter below the minimum threshold, a similar proportion in both age groups had ulnar and/or radial vessels below the minimum threshold.
Discussion

The current study focused on the anatomical suitability of vessels for creation of a WavelinQ. In our practice, patients referred for access surgery routinely undergo preoperative vascular mapping as the standard of care. There is a clinical preference for placing an AVF as the initial access when the vascular anatomy is suitable. Once the WavelinQ device had been approved by FDA in 2018, we modified our vascular mapping protocol to screen for eligibility for an WavelinQ, by adding measurements of the perforator vein (presence and diameter), as well as antecubital fossa measurements of the radial and ulnar veins and arteries. Of 223 patients who were eligible for a surgical fistula (minimum artery diameter of 2 mm and presence of a cephalic or basilic vein with minimum diameter of 2.5 mm), 63% were eligible for the WavelinQ. Older patients were less likely to have a vascular anatomy suitable for a WavelinQ, with the major limiting factor being a perforator vein smaller than the minimum diameter threshold of 2 mm.

Little has been published previously about the suitability of patients with ESKD or advanced CKD for an endoAVF. In the pilot NEAT study that led to the FDA approval of the WavelinQ system, preoperative vascular mapping was not specifically addressed, other than a vague statement that screening failure occurred in 25% of patients due to small target vessel size, without specific mention about the presence or diameter of the perforator vein(16). For a different type of endoAVF, the Elipsys EL system study, screening failure rate was reported as 28%(18). A recent study examined the anatomical suitability for both endoAVF types, and the percentage of anatomically suitable endoAVF was slightly lower than the results of the current study (63%). The former study was limited by measuring venous diameters without a tourniquet. In addition, it was performed at a Veteran Administration hospital, in which the patients were exclusively male and relatively old(19).
The major strengths of the current study include assessment of anatomical suitability for a WavelinQF using a standardized ultrasound technique; a multidisciplinary approach to optimize vascular access outcomes in a large academic center with a diverse patient population; reliance on a small number of highly experienced sonographers and radiologists; and the use of a prospective computerized database to optimize capture of data associated with vascular access care.

Our study also has some limitations. First, the patients were derived from a single large dialysis center, and the results may not generalize to some dialysis centers. Second, we lacked information on the dialysis vintage or number of previous AV access creations in the study population. Finally, this study focused on the technical feasibility of WavelinQ creation, on the basis of meeting the minimal vascular diameters. It does not, however, answer the question about how often the WavelinQ actually achieves clinical maturation, i.e., suitability for dialysis use. We know from published literature that a substantial proportion of surgically created AVFs fail to mature, and that outcomes vary according to patient demographics or co-morbidities. Future studies are required to determine how often endoAVFs fail to mature, and what factors are associated with their success.

**Conclusion**

In a large academic center hemodialysis access, 63% of patients whose vascular anatomy was suitable for creation of a surgical fistula were suitable for the WavelinQ creation. Older patients were less likely to be suitable for a WavelinQ, primarily due to the presence of small perforator veins. Thus, a surgical AVF may be preferred in such patients.
Disclosures

R. Varma reports the following: Speakers Bureau: Becton, Dickinson and Company. M. Robbin reports the following: Research Funding: Philips Medical; Scientific Advisor or Membership: Radiology Editorial Board, Journal of Ultrasound in Medicine Editorial Board, Ultrasound Quarterly Editorial Board. M. Allon reports the following: Consultancy Agreements: CorMedix. Scientific Advisor or Membership: Kidney360 Editorial Board as Editor-in-Chief. The remaining authors have nothing to disclose.

Funding


Author Contributions

Alian Al-Balas: Conceptualization; Data curation; Formal analysis; Methodology; Writing - original draft; Writing – review and editing. Rakesh Varma: Resources; Supervision; Writing - review and editing. Kedar Sharbidre: Resources; Validation; Writing - review and editing. Hassan Al-Balas: Formal analysis; Project administration; Supervision; Writing - review and editing. Ammar Almehmi: Project administration; Supervision; Writing - review and editing. Ahmed Kamel Abdel Aal: Conceptualization; Data curation; Methodology; Writing - review and editing. Michelle Robbin: Validation; Writing - review and editing. Michael Allon: Conceptualization; Supervision; Validation; Visualization; Writing - review and editing.
References

Table 1: Patients with preoperative vascular mapping suitable for a surgical AVF and for WavelinQ endo-AVF

<table>
<thead>
<tr>
<th>N of patients (%)</th>
<th>Surgical AVF eligibility in patients undergoing vascular mapping (n=437)</th>
<th>WavelinQ endoAVF eligibility in patients suitable for a surgical AVF (n=223)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (223(51%))</td>
<td>No (214 (49%))</td>
</tr>
<tr>
<td>Age in years (Mean ± SD)</td>
<td>55±15</td>
<td>57±15</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>150(68)</td>
<td>168(79)</td>
</tr>
<tr>
<td>White</td>
<td>71(32)</td>
<td>39(21)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>118(53)</td>
<td>115(54)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>210(94)</td>
<td>197(92)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>45(20)</td>
<td>42(20)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>15(7)</td>
<td>17(8)</td>
</tr>
<tr>
<td>ESKD</td>
<td>182(82)</td>
<td>187(87)</td>
</tr>
<tr>
<td>AVF location (left arm)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>High radial takeoff</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* Information missing for 9 patients
Table 2. Comparison of deep vein characteristics in older and younger patients evaluated for a WavelinQ endoAVF, n = 223

<table>
<thead>
<tr>
<th></th>
<th>Age &lt;60 yr N=128</th>
<th>Age ≥ 60 yr N=95</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent perforator vein, n (%)</td>
<td>16 (12%)</td>
<td>17 (18%)</td>
<td>0.26</td>
</tr>
<tr>
<td>Perforator vein &lt; 2 mm, n (%)</td>
<td>26 (20%)</td>
<td>36 (38%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Perforator vein ≥ 2 mm, but radial or ulnar artery or vein &lt;2 mm, n (%)</td>
<td>14 (11%)</td>
<td>7 (7%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Unsuitable for WavelinQ for any reason</td>
<td>56 (44%)</td>
<td>60 (63%)</td>
<td>0.004</td>
</tr>
</tbody>
</table>
Figure 1.

(a) Endovascular arteriovenous fistula (endoAVF) creation. Pre-creation venogram demonstrating a direct perforator (yellow arrow) arising from the lateral ulnar vein (white arrow) and draining into the cephalic vein (green arrow). (b) Pre-creation angiogram demonstrating opacification of the radial (blue arrow), ulnar (red arrow) and interosseous (green arrow) arteries without stenosis. The lateral ulnar vein and ulnar artery were selected as target creation vessels. (c) Arterial and venous catheters were advanced to the desired position based on pre-creation venogram/angiogram. Note that the arc of the electrode (green arrow) is congruent with concave surface of the arterial backstop. (d) Fistulogram shows successful endoAVF creation (white arrow) and coil embolization of the brachial vein (blue arrow) to redirect the flow to the cephalic vein and support maturation of the cannulation area.
**Figure 2.**

a. Ultrasound vascular mapping showing suitable mapping for endo-AVF. (Please note ‘Dist’ annotation on the images are Inner diameters). Ulnar artery (UA) and Veins(UV) 2cms caudal to the brachial artery bifurcation. UA diameter of 0.48 cm. b. Radial artery (RA) and Veins(RV) 2cms caudal to the brachial artery bifurcation. RA diameter of 0.43 cm. RV diameters: 0.37/0.44 cms. c. Deep perforator, diameter of 0.24 cm between cephalic vein and ulnar vein
Figure 3. Schematic presentation of patients who underwent preoperative vascular mapping between March 2019 and March 2021

- Artery diameter ≥ 2 mm and Venous outflow (cephalic or basilic) ≥ 2.5 mm

- Perforator vein diameter ≥ 2 mm, ulnar artery and vein ≥ 2 mm OR radial artery and vein ≥ 2 mm