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Original Scientific Paper

ENDOVASCULAR CREATION OF HAEMODIALYSIS ARTERIOVENOUS FISTULA

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SUMMARY – Surgical fistulas have been used to create dialysis access for over 50 years in chronic kidney disease patients. However, due to problems like slow maturation and a high risk of thrombosis or stenosis, results remain sub-optimal with high intervention and surgery rates to maintain patency.

Endovascular methods for fistula creation were invented recently to resolve these issues, allowing haemodialysis patients to have an alternative non-surgical option, with two different devices currently available. Endovascular creation of A-V fistulas is involved with minimal vessel trauma, which could be the reason for encouraging initial results demonstrating high technical success rates, low intervention rates, and good patient satisfaction. This article describes the technical aspects of these procedures, patient selection as well as trial results, and the status of endovascular arteriovenous fistula creation.

Key words: *Chronic kidney disease, Dialysis access, Arteriovenous fistula, Surgery, Endovascular procedures*

Introduction

The prevalence of end-stage renal disease (ESRD) is still increasing in Europe, and vascular access is needed in most of these patients so that kidney function can be replaced by haemodialysis. At the same time, the number of kidney donors is still significantly lower in most countries than the growing incidence of end-stage renal disease (ESRD), despite efforts to increase awareness for this issue[1].

There are three available haemodialysis access modalities, which include arteriovenous fistula (AVF), arteriovenous fistula graft (AVG), and indwelling central venous catheter (CVC). Among all these AVF is associated with the lowest mortality, morbidity, and cost[2-4].

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Brescia and Cimino first invented a surgical technique for AVF creation, which has set the base for thousands of procedures in the next 50 years and is the main option for dialysis access. Still, even with all advances in surgical methods, vascular access for haemodialysis remains its weakest point as it is the leading cause of hospitalization in these patients[5-7].

AVF formation is the currently recommended access due to its proven lower mortality, morbidity, and cost compared with other solutions (8-10). However, between 20 and 60% of fistulas after surgical creation do not successfully mature or become unsuitable for haemodialysis. In the end, they become dependent on CVC, which is associated with higher morbidity [11].

Studies suggest that dialysis AVF usually requires up to 3 additional surgical or radiological interventions to secure its usability. This, in addition to other mentioned problems, leads to lower patient satisfaction and willingness to undergo such procedures [11-13].

Despite modern surgery attempts to create the ideal AVF, creation, maturation, and duration remain

unpredictable and difficult. One of the important but underestimated issues with dialysis is the fact that often with patients with borderline end-stage renal disease, it is hard to predict when vascular access will be needed and when dialysis will be initiated. Evidence is lacking on when it is the optimal time to create fistulas, and the Fistula First, Catheter Last initiative recommends the formation of fistula 6 months prior to the expected dialysis (14). However, with the changing and unpredictable dynamics of renal disease, there can be disparities in the need for vascular access and AVF or graft formation, with up to 17% of patients never using their AVF due to slower progression to end-stage renal disease, or up to 80% of patients still initiating their dialysis with a CVC (15). Even though AVF remains the most often used vascular access with 64% of patients using it, compared to 16.6% using grafts and 18.9% with CVC, the Dialysis Access Consortium data showed that up to 60% of AVFs are not suitable for dialysis at 6 months, which is either due to failure to mature initially or very often due to venous stenosis and thrombosis [16,17].

On the other hand, AV grafts and tunnelled catheters can be placed and used quickly and used right away. However, both are connected to significant complications like infection or thrombosis and show reduced durability compared to AVF.

It is believed that the mentioned problems with maturation and duration of surgical AVF occur due to specific changes that are present in the vascular biology and vascular flow dynamics, which are still largely not understood. These processes include a reduction of luminal diameter due to neointimal hyperplasia and insufficient outward remodelling (18). Most of the efforts to advance in this area are focused on optimizing fistula maturation. Studies have shown that most fistulas have problems maturating due to neointimal hyperplasia at the juxta-anastomotic vein site, which is the result of endothelial and smooth-muscle injury from shear stress, turbulent flow, and tissue injury at the time of surgery (19). This process can trigger certain cellular and molecular mechanisms with the activation of myofibroblasts and fibroblasts within the endothelial wall, migrating from the media to the intima along with local inflammation and oxidative stress [20].

Proper artery and vein selection can also be a factor causing inadequate AVF function, as the chosen vessels can be of an inadequate size or positioned too deep. Recommended vein diameter for AVF is 0.25cm and artery diameter of 0.2cm, with vessels superficial enough to be easily palpable after maturation[21].

Except for the mentioned cellular mechanisms occurring in neointimal hyperplasia, it is suspected that hemodynamic stress from turbulent vascular flow at the anastomosis site causes stenosis. Furthermore, vascular manipulation during the surgery itself is a very likely but underestimated cause of venous injury leading to stenosis and delayed maturation [22]. The advances in vascular surgery over the past decades still have not been able to find an effective solution for this problem.

Dialysis AV grafts, used more in some countries, also develop venous stenosis due to neointimal hyperplasia. The artificial graft material is also more susceptible to thrombosis and infection, making the graft an inferior choice between these two surgical options.

For all these reasons, a demand was recognized for creating new vascular access creation options, which would be less invasive and possibly more durable than the established surgical methods. Devices that have been tried out in the past showed limited success, but recently new technologies have demonstrated the potential to change the conventional algorithm for dialysis access. The endovascular approach has been used more often recently in various fields of medicine, thereby creating a less invasive option for some conditions that were considered treatable only by surgery. This idea was also implemented in the arteriovenous access for renal disease. In the last two decades, endovascular methods such as stenting for central venous stenosis and angioplasty for fistula maturation and proximal venous stenosis were increasingly used and now stand as the first therapy option for primary AV fistula pathology and insufficiency. The next step was creating an AVF using an endovascular approach as this may reduce vessel trauma and thereby reduce neointimal hyperplasia leading to maturation failure. Also, the fact that endovascular procedures minimize patient discomfort and hospital stay present a benefit that can improve patient acceptance and fistula use.

Endovascular arteriovenous fistula creation for haemodialysis access

Interventional radiologists performing haemodialysis access interventions on a regular basis can find the

idea of percutaneous AVF creation as a potential finishing touch to the complete service that is provided to this group of patients. This idea has become a real option within the past years, and there are currently two devices being used with available results from multiple studies.

Both available options for percutaneous AVF creation are based on the same concept that vessels are not clamped, mobilized, dissected, or sutured. Both systems use heat in the form of radiofrequency to create anastomosis. They create an anastomosis, which is located in the deep vascular system, between the artery and its two concomitant veins. This anastomosis is usually located in the proximal forearm, slightly distal to the perforating vein.

Both procedures require a detailed analysis of the vasculature before preparation and patient selection. The main decisive factor for percutaneous AVF creation is assessing the venous perforator close to the cubital fossa that connects the deep and superficial veins. The size of the vessels is also noted in the examination and, similar to the surgical approach, should include a 2 mm artery and vein, which should also have a straight parallel configuration for a good result. The perforating vein is sometimes difficult to analyse and find due to its frequent anatomical variations and duplications.

Percutaneous fistula is basically formed between the radial artery and vein or the ulnar artery and vein in the forearm near the cubital fossa, where the deep veins are connected to the superficial system through the perforator (23). The surgical procedure that somewhat resembles this concept is the Gracz fistula, in which the brachial artery is connected with the venous perforator [24].

Devices for AVF creation

There are currently 2 devices that have been certified by Conformité Européenne and approved by US FDA to create an AVF through an endovascular approach: the everlinQ/WavelinQ endoAVF system (TVA Medical, Becton Dickenson and Company, Franklin Lakes, NJ) and the Ellipsys Vascular System (Avenu Medical, San Juan Capistrano, CA). An overview of the main characteristics of both systems is shown in Table 1.

The everlinQ endoAVF system is based on two catheters that contain rare earth magnets at their tips. The first-generation device consisted of two 6 Fr catheters, which were inserted via the upper arm into the artery and accompanying vein. In 2017 a device with 4 Fr catheters has replaced the old 6 Fr system in Europe, which allowed the use of radial or ulnar approach in most patients. One magnetic catheter is inserted into the ulnar or radial artery, while the other is inserted into the ulnar or radial deep vein with the help of ultrasound guidance. When the catheters are aligned with one another under fluoroscopic guidance, the magnets embedded within the catheters are attracted and aligned, simultaneously aligning a radiofrequency electrode in the venous catheter and a ceramic backstop in the arterial catheter. The heat created by the radiofrequency electrode, which is then released from the venous catheter, burns a channel for about 1-2 seconds, creating a 5 mm × 1 mm side to side anastomosis between the artery and vein. The result is usually confirmed by angiography. A usual mild complication seen right after the creation is a vessel spasm triggered by thermal effects or electrical stimulation, but it usually resolves itself soon after the procedure. Most procedures require additional coil embolization of the deep brachial vein proximal to the anastomosis and the perforating vein in order to increase the outflow into the superficial veins used for dialysis access. The procedure is performed under light sedation with local anaesthesia administered at the puncture site.

The Ellipsys Vascular Access System involves a thermal resistance anastomosis device (TRAD) [25] that creates an AVF using a single 6 Fr catheter that thermally connects the vessels. One of the main differences to the previous device is that most procedures use ultrasound guidance alone without radiation exposure and contrast media. At the same time, this procedure requires the operator to have good ultrasound guidance experience and skills in order to perform the procedure adequately. A puncture of a superficial vein (cephalic or basilic) is made in the upper arm. From there, the device is navigated in retrograde fashion through the perforator to the deep venous system and then continues into the radial artery through its wall. A guidewire is then placed, and the Ellipsys device is inserted over it and advanced to the artery. The device catheter has two contact plates where one is placed in the vein and the other in the artery. Radiofrequency is

Table 1. Percutaneous AVF creation systems characteristics, criteria and results

Endovascular system	EverlinQ	Ellipsys
Number of necessary vascular accesses	2	1
Possible anastomosis locations	Ulnar A-V Radial A-V Brachial A-V	Perforating vein – radial A
Additional interventions	Coiling of the deep vein proximal to the anastomosis	PTA of the anastomosis
Technical success	98% (NEAT) 97% (FLEX) 100% (EASE)	95% (PIVOTAL) 88% (TRAD)
Cumulative patency	84% (NEAT) 96% (FLEX) 87% (EASE)	86,7%(PIVOTAL) 75% (TRAD)
Imaging guidance	Ultrasound for access Fluoroscopy for procedure	Ultrasound for access and procedure Fluoroscopy for PTA
Anatomic inclusion criteria	Presence of deep perforating vein Brachial artery >2 mm, radial or ulnar artery >2 mm at the anastomosis and access Radial/ulnar/brachial vein >2 mm at the anastomosis and access Distance between proximal radial/ulnar artery and vein (anastomosis site) <1 mm	Presence of deep perforating vein Perforator diameter >2 mm Proximal radial artery lumen diameter >2 mm at the anastomosis Distance between the perforating vein and radial artery <1.5 mm

used to create heat up to 15 seconds before the system is removed. Even though angiography is usually not needed to perform this procedure after the AVF creation, in most cases, an additional PTA is performed at the anastomosis site. After the Everlinq procedure, PTA is never recommended right after the procedure due to the fragility of the fresh anastomosis. Coiling of the deep vein system is performed only in exceptional cases and is usually not needed, like with the EverlinQ device.

Clinical results of the everlinq and ellipsys devices

The first trial evaluating the clinical results of the everlinQ endoAVF system was the FLEX study.

This prospective study enrolled 33 patients and reported a 97% technical success rate, 58 days to maturation, and 96% of fistulas were considered mature and usable for dialysis after 3 months. Technical success was achieved in 32 out of 33 cases (97.0%) [26].

The second important study that evaluated this system in a multinational and multicentre trial was the Novel endovascular access trial (NEAT), which involved 80 patients who were treated using the 6Fr system. A high technical success rate of 98% was reported. The endoAVF was considered physiologically suitable for dialysis within 3 months if brachial artery flow ≥ 500mL/min and vein diameter ≥ 4mm. This was achieved in 87% of patients. Reported 12-month primary and cumulative patencies were 69% and 84%, respectively, with 8% of patients experiencing serious adverse events [27]. A single-centre observational study of WavelinQ for the 4F device with 12 months of follow-up in 30 patients compared endovascular AV fistulas with radiocephalic arteriovenous fistulas and found that primary patency at 6 and 12 months was greater in the WavelinQ group (65.5% at 6 months and 56.5% at 12 months) compared to the surgical group (53.4% at 6 months and 44% at 12 months) which would support that WavelinQ endovascular arteriovenous fistulas may be considered as a first option in the access pathway particularly if vessels at the wrist are absent or less than ideal [28].

The EASE study reporting data from the newer 4Fr system is a multioperator, single-center, single-

arm, prospective study that included 32 patients with radial or ulnar access procedures. The technical success rate was 100% and primary and cumulative patency rates through 6 months were 83% and 87%.

The published results involving the Ellipsys device included 2 main studies. In the first study, 26 patients underwent creation of AVF, with a success rate of 88% (23 of 26 patients) [25]. At 6 weeks, 87 % of the AVF were patent, and 80% were used for HD at 3 months. To improve the maturation of the shunts, 48% of the patients had to be treated with an additional PTA. However, in 87% of cases, additional procedures were needed, involving balloon dilation, vein embolization, vein ligation, venous transposition, and valvulotomy.

The second published report involved a multicentre US study. It reported a technical success rate of 95.0% without reported serious adverse events. Haemodialysis could be achieved in 88.0% of the patients. This study also required significant additional interventions to enable maturation of the shunt, including 113 PTAs and 42 coil embolizations of the deep venous system.

A 2018 study showed results from 34 included patients, with similar results: a technical success of 96% and a cumulative patency rate of 92% (141 days average follow-up) [30].

A most recent single centre, single operator retrospective review of 100 patients treated with endovascular AVF creation (65 Ellipsys and 35 WavelinQ patients) showed the technical success of the Ellipsys and WavelinQ to be 100% versus 97% with median procedure times of 14 versus 63 minutes. Successful pAVF dialysis was established in 31 of 39 patients (79.5%) versus 14 of 24 patients (58%), respectively. Secondary patency at 12 months was significantly higher among patients who had an Ellipsys procedure (82%) than among those who underwent the WavelinQ procedure (60%) [31].

Discussion

The usual order of preference for the dialysis access in end-stage renal disease patients involves the distal radial-cephalic fistula, a brachial-cephalic fistula, and a transposed brachial-basilic fistula, so the addition of a percutaneous approach to the proximal radial and ulnar AV fistulas presents 2 valuable new options with proximal vessel preservation. The endovascular fistula creation also has the benefit of avoiding a surgical procedure and with-it vessel manipulation, suturing, and trauma, all of which may contribute to the failure of AVF. Another potential benefit of the endoAVF over surgical AVF is the reduced need for interventions to mature access and maintain function. By contrast, the endoAVF procedure minimizes vessel trauma, potentially lessening the stimulus for negative remodelling, leading to frequent reinterventions. The benefit of a lower intervention rate after percutaneous fistula creation has been explored by comparison with both propensity score-matched Medicare and the United States Renal Data System cohorts of patients with surgical AVF [32]. That comparison reported a significantly lower rate of interventions and care costs within the first year of creation with endoAVF relative to surgical AVF. Also, a reported lower re-intervention rate could lead to minimizing the mentioned surgical fatigue cited by some patients as the reason to choose a central catheter over a surgical creation of a new fistula. All these potential benefits of the endovascular approach to fistula creation position it in the same conversation with surgical techniques as a possible primary option to create functional vascular access.

Certain longstanding principles will still not be changed – those patients who are ideally suited for a surgical radiocephalic fistula will still be treated in the standard fashion. However, patients who are not candidates for a radiocephalic fistula, as well as patients with failed radiocephalic AVF, may find endovascular AVF creation to give them an option to receive a functional AVF while preserving more central options for future access. The goal of these new minimally invasive procedures is not to completely replace surgical AVF but to provide a new anatomic location for AVF placement with possibly less need for reintervention and earlier maturation.

Conclusion

Haemodialysis access remains a complex problem for patients with end-stage renal disease. In recent years, two new devices for minimally invasive endovascular fistula formation have been introduced to overcome poor surgical AVF outcomes when it comes to maturation and need for reintervention and also to give patients additional anatomic locations.

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Sažetak

ENDOVASKULARNO KREIRANJE DIJALIZNE ARTERIOVENSKE FISTULE

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Kirurški napravljene fistule se koriste više od 50 godina za stvaranje pristupa za dijalizu kod pacijenata s kroničnim bubrežnim zatajenjem. Međutim, zbog problema kao što su dugotrajna maturacija te visok rizik tromboze ili stenose rezultati ostaju suboptimalni s učestalim reintervencijama i operacijama kako bi se održala prohodnost fistule. Kako bi se premostilo ove nedostatke od nedavno su stvorene endovaskularne metode za kreiranje fistula, što pacijentima na dijalizi daje dodatnu nekiruršku opciju, s dva različita trenutno dostupna sustava.Endovaskularno kreiranje A-V fistule je povezano s minimalnom traumom krvnih žila što može biti razlog za ohrabrujuće rane rezultate, koji pokazuju visoku stopu tehničke uspješnosti, nisku stopu reintervencija uz dobro prihvaćanje od strane pacijenata.

U ovom radu opisujemo tehničke aspekte ovih zahvata, pravilan izbor pacijenata kao i rezultate istraživanja te trenutni status endovaskularnog zahvata stvaranja arteriovenske dijalizne fistule.

Ključne riječi: *kronična bubrežna bolest, pristup za dijalizu, arteriovenska fistula, kirurgija, endovaskularna procedura*