Original Article

Clinical hemodialysis experience with percutaneous arteriovenous fistulas created using the Ellipsys® vascular access system

Hedia HEBIBI,[1,2,3] Jedjiga ACHICHE,[2] Gilbert FRANCO[4], Jacques ROTTEMBOURG[5]

[1]Department of Nephrology and Dialysis, Hôpital Privé de Thiais, Thiais, [2]Dialysis Unit NephroCare Bièvres, Bièvres, [3]Dialysis Unit NephroCare Villejuif, Villejuif, [4]Department of Vascular Medicine, Clinique Arago and [5]Department of Nephrology, Groupe Hospitalier Pitié-Salpêtrière, Paris, France

Abstract

Introduction: The aim of this study is to report our clinical hemodialysis experience using a percutaneous arteriovenous fistula (pAVF) created with the Ellipsys® vascular access system. This pAVF device creates a permanent AVF anastomosis between the proximal radial artery (PRA) and the deep communicating vein (DCV) in the proximal forearm.

Methods: The medical records of all patients with a pAVF were retrospectively reviewed. The clinical data analyzed included reliability of pAVF use, quality of dialysis, rate and success of puncture, and pAVF related complications, along with incidence of subsequent interventions.

Findings: Between May 2017 and November 2018, 34 patients had a pAVF created with technical success in 33 patients (97%). Twenty-eight out of 34 (82%) patients had successful two-needle cannulation within 10 days to 6 weeks after pAVF creation. The mean Kt/v was 1.6 (1.2-2) and the average recirculation was 10%. Fifteen patients (44%) needed no further access intervention. Twelve patients (35%) required an additional procedure to assist maturation of the pAVF in order to facilitate puncture. The average blood flow measured at the brachial artery, before the first cannulation, was 850 ml/min. From causes unrelated to the procedure, four patients died during the follow-up study. Two patients required revision to a surgical AVF. None of the pAVFs developed aneurysmal degeneration steal syndrome, or high access flow related issues.

Discussion: The Ellipsys® pAVF offers a safe and functional vascular access for hemodialysis. Advantages included prompt access maturation, avoidance of high flow AVFs, and a simple nonsurgical procedure with high patient satisfaction. Functional outcomes are equivalent and likely better than surgical fistulas. There appears to be less aneurysmal degeneration and need for future reintervention. Objective dialysis parameters indicate excellent quality of hemodialysis for the patient.

Keywords: percutaneous, arteriovenous fistula, Ellipsis®, endovascular, hemodialysis

INTRODUCTION

Hemodialysis (HD) requires reliable vascular access that is best provided by an arteriovenous fistula (AVF), with sufficient flow that is easily cannulated and able to be used several times per week. AVFs are preferred over

Correspondence to: Hedia HEBIBI, Dialysis Unit NephroCare Villejuif, France, 1 Mail du Professeur Georges Mathé Villejuif 94800, E-mail: had.hebibi@gmail.com

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synthetic grafts and central venous catheters (CVC) because of their lower rate of infection, hospitalization, and healthcare costs.[1] The use of ultrasound and endovascular interventions have gained an important role in AVF creation and maturation with the goal of meeting the rule of sixes: flow rate of at least 600 ml/min, vein diameter of at least 6 mm, with a maximum depth of the vessel of 6 mm.[2]

Surgical arteriovenous fistula (sAVF) creation was described more than 60 years ago with increasing complexity in autogenous access procedures but with little conceptual evolution as first established.[3] A new device has been recently developed for percutaneous AVF (pAVF) in the proximal forearm, creating the anastomosis through tissue fusion between the proximal radial artery (PRA) and the deep communicating vein (DCV).[4] Herein, we report our clinical results of dialysis in patients that had a pAVF created with the Ellipsys device.

MATERIALS AND METHODS

Study population

All patients that had a pAVF creation with the Ellipsys® vascular access system (Avenu Medical, San Juan Capistrano, CA, USA) were included in this analysis. The patients included were not good candidates for a wrist fistula and met the anatomic criteria for the Ellipsys device (distance between DCV and PRA <1.5 mm, DCV and PRA diameter ≥ 2 mm). The patient exclusion criteria were after AVF surgical failure creation patients who had another type of surgical AVF creation during this period. However, the patients who had a pAVF after surgical failure creation were included in our study. Anatomical eligibility was confirmed by the operating vascular surgeon using duplex ultrasound examination preoperatively (Fujifilm SonoSite Ltd., Hitchin, UK). The arterial and venous anatomy for both upper extremities were evaluated in order to identify the best possible site for AVF creation in terms of future functional patency and avoidance of need for multiple re-interventions to achieve maturation. As required by law, only oral approval was necessary and obtained from the patients. As it was an observational study, it did not require approval of the relevant Ethics Committee, according to French regulations.

Patients' characteristics and comorbidities

The study population included a total of 34 patients with end-stage renal disease who had a pAVF creation. Twenty patients (58%) were male, and the average age was 62 years (range 26-84). Twenty two patients (65%) were caucasian and 12 patients were of African origin. Twelve patients were diabetic and obese, and 10 patients had a previous central catheter in place before the pAVF creation. Patients' characteristics are summarized in Table 2.

Technique

The technique and the criteria for patient eligibility have been previously described.[4] In brief, the pAVF is created with a single superficial vein puncture at the level of the elbow advancing the needle through the DCV in the proximal forearm, then puncturing the PRA and placing a guide wire into the artery (Figure 1).

The Ellipsys® device uses a single catheter to create a secure thermal fused anastomosis between the PRA and DCV (Figures 2a, 2b, and 2c). The procedure is accomplished entirely under ultrasound guidance without need for radiation exposure. The duration of the procedure is generally 15–20 minutes and it may be completed in an outpatient surgery department, or in an office procedure settings. Due to its unique anatomic position, the DCV flows from the deep veins of the forearm to the superficial venous system allowing for maturation of the cephalic and/or the median cubital vein(s). The combination of leaving both outflow veins open and the lack of a surgical incision results in an important additional length for cannulation and less pressure in the dual outflow tract. This modest flow and pressure system should result in less access complications and need for interventions. After removal of the Ellipsys® device, angioplasty balloon dilatation of the anastomosis using the pAVF procedure guide wire allows for immediate improvement of flow and acceleration of maturation if needed.[5]

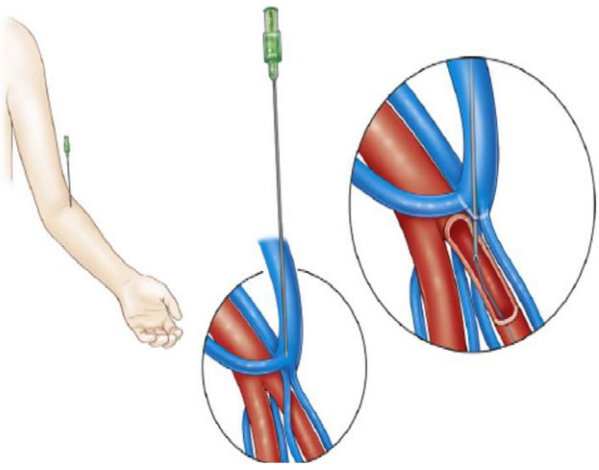

Figure 1 A guide wire is placed through the communicating vein at the antecubital fossa into the proximal radial artery. [Color figure can be viewed at wileyonlinelibrary.com]

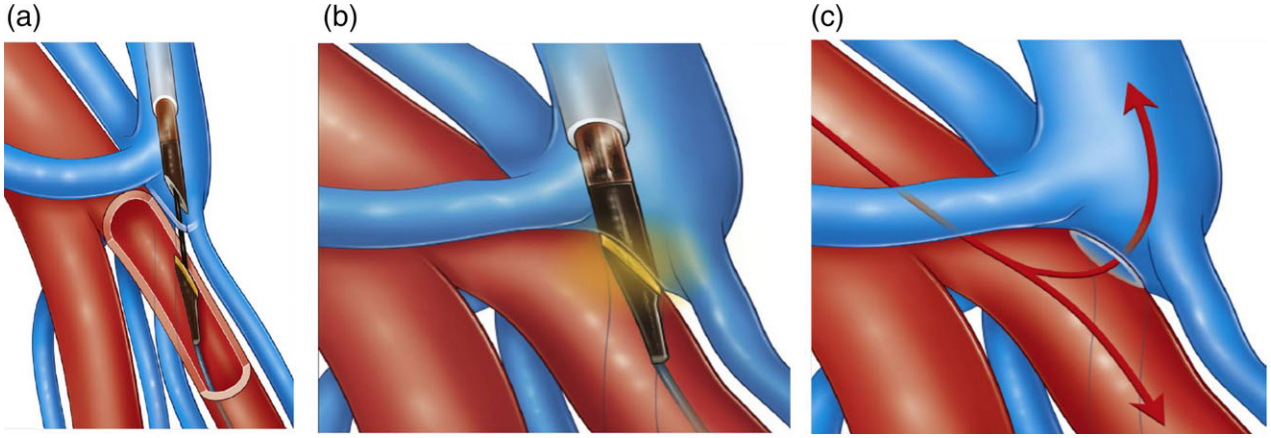

Figure 2 (a) The percutaneous AVF Ellipsys device is advanced with the distal portion of the device in the proximal radial artery and the base of the device remaining in the deep communicating vein. (b) The Ellipsys device is closed and the power controller activated. Low power thermal energy and pressure fuse a secure AVF anastomosis. (c) The anastomosis between the proximal radial artery and the deep communicating vein is completed. [Color figure can be viewed at wileyonlinelibrary.com]

RESULTS

Twenty four patients (24/34) had successful two-needle cannulation within 10 days to 6 weeks post creation. There were no serious puncture related complications. A two-needle puncture of the cephalic vein (9 patients) or a combination of median cephalic and medial cubital vein cannulation (15 patients, 44%) was used. In our study, we used plastic needles Clampcath 16 gauge 25 to initiate the puncture, then Clampcath 15 gauge 25 to optimize the pump blood flow. This type of needles did not damage the fistula and preserved the veins. Five patients had a Button-hole cannulation established within 4 weeks after starting puncture. Six patients had ultrasound guided puncture for the first sessions in order to facilitate puncture and educate the nurses. All patients had cannulation sites marked by the operating surgeon during regular postoperative evaluations using clinical and ultrasound examination. Fifteen patients (44%) required no further intervention. Twelve another patients (35%) required secondary dilatation by angioplasty within 3–4 weeks to assist maturation to remove flow and to facilitate puncture. One of these patients also required a banding of the median cubital vein to increase blood flow into the cephalic system without sacrificing the median cubital or basilic veins, while maintaining those cannulation sites. One patient had a percutaneous valvulotomy at the time of pAVF creation to recruit forearm access sites. There were two access related complications during the study period. Two patients experienced cannulation difficulties, resolved by converting the pAVF into a surgical fistula. Only two individuals required AVF outflow superficialization. None of the pAVFs developed aneurysmal degeneration. Patient follow-up was 1–18 months (Mean = 14 months).

Table 1 Comparison between surgical and percutaneous arteriovenous fistula (pAVF)

	Surgical AVF	Percutaneous AVF
Skin	Scar	No scar
Anatomy	All types of AVF	Radio-cephalic proximal fistula
Blood flow	Variable	Immediately adequate after anastomosis dilatation
Cannulation	Generally one targeted outflow vein	Often two outflow veins (cephalic and median cubital)
Operative follow-up	Surgical incision care	No incision care
Post -creation procedures and cost expectations	High	Low
Complication risks	Aneurysm, Stenosis, steal.	Far fewer complications

Table 2 Characteristics of patient's demographics

Patient	Age	Sex	Co-Morbidity dit	Localization of pAVF (right/left)	Previous Fistula	Previous catheter	Cannulation time 2 needles	Blood flow After creation ml/min	Blood flow at one month ml/min	Blood flow at 3 months ml/min	Blood flow at 6 months (ml/min)	Action performed To accelerate maturation
1	62	M	Diabetes, HT	Left radio-cephalic	No	Yes	28 days	700	1100	1100	1100	ATL one week after surgery
2	65	M	HT, diabetes, obesity	Right radio-cephalic	No	Yes	28 days	600	1120	1150	1100	Immédiate ATL after surgery
3	84	M	HT	Right radio-cephalic	No	Yes	21–28 days	650	700	1000	900	Binding of basilic vein
4	55	F	HT, obesity	Right radio-cephalic	No	No	20 days	630	780	950	920	Immédiate ATL
5	55	M	HT	Right radio-cephalic	No	YES	10 days	568	880	900	1120	Angioplasty
6	65	M	Diabetes, HT	Left radio-cephalic	No	Yes	4 weeks	300	660	780	860	Immediate ATL
7	77	M	Diabetes, HT, obesity,	Left radio-cephalic	No	Yes	21 days	500	790	800	990	Immediate ATL
8	55	F	HT, obesity	Left radio-cephalic	No	Yes	21 days	500	660	830	912	None
9	79	M	HT, diabetes	Left radio-cephalic	No	Yes	22 days	628	690	700	960	Angioplasty
10	53	M	HT	Right radio-cephalic	No	No	35 days	650	770	880	1090	
11	63	M	HT	Right radio-cephalic	No	No	28 days	658	750	760	1100	Valvulotomy
12	60	F	HT, uropathy	Left radio-cephalic	Yes	Yes	30 days	460	470	–	–	sAVF in the same site of pAVF
13	26	M	HT	Left radio-cephalic	Yes	No	22 days	588	620	400	870	Thrombectomy
14	57	M	HT	Left radio-cephalic	Yes	No	37 days	670	700	710	–	sAVF in the same site (deep vein)
15	62	F	HT	Left radio-cephalic	No	Yes	36 days	490	520	688	790	Angioplasty
16	63	M	HT	Left radio-cephalic	No	No	40 days	520	650	690	688	Angioplasty
17	57	M	HT	Left radio-cephalic D	No	Yes	45 days	490	590	710	777	Angioplasty
18	63	M	HT	Left radio-cephalic	No	No	33 days	560	546	680	790	Angioplasty
19	51	F	HT, Diabetes	Right radio-cephalic	No	Yes	46 days	660	677	800	833	Angioplasty superficialisation
20	68-_	M	HT, obese	Left radio-cephalic	No	No	44 days	560				
21	50	M		Right radio-cephalic	Yes	Yes	28 days	760	77O	790		Superficialisation
22	56	M	Diebetes, obese, HT	Right radio-cephalic	No	Yes	40 days	550	680			
23	66	M	HT	Left radio-cephalic	No	Yes	28 days	620	666			
24	68	M	HT	Left radio-cephalic	No	Yes	33 days	700	780			
25	56	M	Diabetes, obese, HT	Right radio-cephalic distal	No	Yes	44 days	560	690	747		Angioplasty
26	57	F	HT, uropathy	Left radio-cephalic	No	Yes	38 days	680	677	720		
27	68	F	Diabetes, obese, HT	Left radio-cephalic	No	Yes	28 days	744	764			Angioplasty
28	31	F	HT,	Right radio-cephalic	No	Yes	33 days	640	570			
29	40	F	HT	Left radio-cephalic	No	Yes	42 days	470				
30	71	F	HT	Left radio-cephalic	No	No	33 days	430	650			angioplasty
31	59	F	HT, Diabetes	Right radio-cephalic	No	No	56 days	510				
32	76	F	HT,	Left radio-cephalic	No	No	40 days					
33	69	F		Left radio-cephalic	No	No	35 days					
34	72	F	Diabetes, HT	Right radio-cephalic	No	No	42 days					

M = male; F = female; HT = hypertension; ATL = angioplasty with a balloon catheter.

Monitoring of hemodynamic dialysis parameters

The pump blood flow, recirculation rate, venous pressure, and the Kt/v ratio were measured during dialysis sessions using a Diascan 5008 Fresenius dialysis and Evosys generators. All patients had satisfactory qualitative dialysis parameters (average Kt/v = 1.6, recirculation rate = 10%, bleeding time < 10 min). In addition, 20 patients were treated on hemodiafiltration and had re-infusion volume, volume more than 21 liters per session.

Each patient had adequate pump blood flow of 300–350 ml/min and normal arterial and venous pressures throughout the sessions.

Monitoring of pAVF blood flow

Blood flow was measured in this cohort, immediately after pAVF creation, at 1 week, 1 month, 3 months, 6 months, and at 1 year (ultrasound brachial artery flow). The average blood flow was (670 ml/min) at 3 months, (790 ml/min) at 6 months and (800 ml/min) after one year. At the final follow-up exam, the mean accessblood flow, using brachial artery flow to evaluate the total AVF outflow was (907 ml/min). None of the patients developed excessive blood flow or steal syndrome (Table 2).

DISCUSSION

A recent publication, Hull et al. described the results of the Pivotal Multicenter Ellipsys® trial with a successful pAVF creation in 95% (102/107) of patients.[4] Maturation procedures in that study included anastomotic balloon dilatation in 72%, brachial vein embolization in 32%, cubital vein ligation in 31%, and surgical transposition in 26%. Primary blood flow and diameter endpoints were achieved in 86% of patients. Mallios et al.[5] described a modified and improved technique with immediate percutaneous translumunal angioplasty (PTA) of the anastomosis while avoiding brachial vein coiling or branch ligation. Utilizing both cephalic and median cubital veins for cannulation greatly reduced the need for outflow superficialization. The addition of buttonhole cannulation and selective ultrasound guided initial puncture for the patients in this study has resulted in very encouraging results. Rajan et al., using a different system for pAVF creation, reported 33 patients with a pAVF maturation mean time of 58 days (range 37–168 days) with one serious procedure-related adverse event and five minor procedure-related adverse events.[6] Several authors have noted a low risk of proximal radial artery access-related steal syndrome and reported more moderate AVF flow volume compared with AVFs based on the brachial artery.[7–9]

The absence of a visible scar with pAVF is particularly important to many patients for aesthetic reasons. In addition, the modest flow and lower pressure Ellipsys pAVF result in a less noticeable vascular access for individuals who are embarrassed by the visibility of surgical AVFs. However, the absence of an incision and scar requires the particular attention of nurses (and patient education) in order to avoid inadvertent intravenous cannulation by non-dialysis staff for blood tests and/or the taking of arterial pressure on the pAVF extremity (Table 1).

The practice of the nephrologists in this study has been to be in attendance for the first AVF cannulation, and to supervise the initial punctures. With the use of the surgeons' markings after the postoperative clinical and ultrasound examination of the arm, we are able to reliably perform the puncture. During the first hemodialysis sessions, the pump blood flow should be progressive, as for any new fistula, and guided by the venous pressures. This is a key element in beginning reliable cannulation procedures and the detection of possible complications.

The puncture location and cannulation technique of pAVF varies depending on the development of drainage veins and the doppler ultrasound examination. These moderate flow pAVFs, many with dual outflow, are less pulsatile than typical brachial artery based AVFs. An outflow venous tourniquet helps with access puncture along with cannulation education and instruction for the nursing staff about this particular vascular access. Nephrologists should understand the anatomy of the venous drainage of the fistula to guide punctures. We feel these lower pressure and modest flow pAVFs may produce fewer aneurysms and present less outflow turbulence and shear stress vein to the vessel wall.

Compared to a proximal radial artery sAVF,[10,11] where the vascular surgeon may ligate the median cubital vein when the cephalic vein is the dominant cannulation target, the current Ellipsys pAVF technique purposefully leaves both outflow branches open. This offers more options for cannulation and divides pressure and flow between the two vessels. In uncommon cases where cannulation or maturation issues occur, a subsequent ligation or banding of one of two veins is always possible, if needed, to augment flow into a single vessel. During maturation follow-up, ultrasound flow evaluation with digital compression of the median cubital and alternately, the cephalic vein, usually clarifies such issues.

One of several important differences between a sAVF and the pAVF, is that the Ellipsys AVF has multiple

potential outflow cannulation veins, including the cephalic, the medial cubital vein and in some patients, retrograde flow into forearm veins. Therefore, different cannulation options and techniques may be available for use and maintenance of the pAVF (Table 1). Identification of available cannulation options is facilitated by the use of ultrasound imaging.

Excessive AVF flow is rarely noted through the brachial veins and coils or ligation of the brachial vein(s) are almost never necessary. During dialysis the pump will create negative pressure at the site of the arterial puncture and flow patterns will change, with almost all deep vein pAVF flow directed back to the arterial line. After dialysis, blood flow resumes through different vessels. We find this mechanism to be protective rather than problematic as long as proper cannulation and dialysis are easily and reliably achieved. In dialysis units that eventually adopt a complete ultrasound guided puncture protocol of all AVFs; we feel that current problems relevant to a vein's size, depth or tortuosity will be uncommon.

Early cannulation was possible in several patients but used in only selected individuals to avoid a new catheter placement. It appears that the immediate PTA of the anastomosis in combination with the superficial location and adequate size of the median cephalic and medial cubital veins left undisturbed during pAVF creation will allow for early cannulation in a cohort of patients with the potential to avoid a dialysis catheter.

Limitations of this present study include the retrospective single arm observational nature, the relatively small number of patients, and short follow-up.

CONCLUSION

Percutaneous creation of an Ellipsys proximal radial artery fistula is a new and innovative technique, providing reliable vascular access with excellent quality of hemodialysis and without an incision or scar. There were no aneurysmal degenerations and a low rate of interventions required for maturation. Patient satisfaction has been very high. Coupled with selected ultrasound guided puncture, the multiple pAVF outflow veins low-pressure approach offers a promising new concept in creating a reliable and functional vascular access. This new device and technique may improve the way hemodialysis is provided in the future by simplifying the process of AVF creation and maintenance. Larger and longer prospective studies are required to confirm the above findings.

AUTHORS' CONTRIBUTION

HH performed data collection, writing, final approval and overall responsibility of the article. JA performed data collection. GF performed the doppler ultrasound measures. JR performed writing and final approval of the article.

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