Comparison of Surgical Versus Percutaneously Created Arteriovenous Hemodialysis Fistulas

Clinical Paper Review
Prepared by PVH Scientific Communications *for Health Care Professionals*

AUTHORS Harika G, MD; Mallios A, MD; Allouache M, MD; Costanzo A, MD; de Blic R, MD; Boura B, MD; Jennings WC, MD.

JOURNAL *Journal of Vascular Surgery* published online Feb. 2021 DOI: https://doi.org/10.1016/j.jvs.2020.12.086jvs.2020.12.086

Purpose:

To compare outcomes between patients with a percutaneously created arteriovenous fistula (p-AVF) made with the Ellipsys™ vascular access system and patients with a surgically created arteriovenous fistula (s-AVF).

Methods:

Single-center, retrospective comparative study

The primary endpoints:

- Maturation: defined as AVF usage for patients already on hemodialysis, or for patients not yet undergoing hemodialysis, by clinical examination and >4 mm diameter and >500 mL/L of flow per ultrasound
- Primary patency: defined as the interval between AVF creation and any intervention (open or percutaneous) to maintain or reestablish access patency
- Secondary patency: defined as the interval from access placement to access abandonment

The secondary endpoints:

- Incidence of reinterventions (required for assisted maturation and/or AVF dysfunction) and complications (including wound healing issues, infection, incidence of steal syndrome and aneurysm formation)

The following comparisons were performed:

- p-AVF (Ellipsys system) vs. s-AVF
- Subgroup analyses performed:
  - p-AVF (Ellipsys system) cohort vs. subgroup of surgically-created AVFs at level of the elbow
  - p-AVF (Ellipsys system) cohort vs. subgroup of surgically-created AVFs at level of the wrist
- A learning curve effect was assessed in the p-AVF (Ellipsys system) cohort by comparing outcomes of the early (the first 50) procedures to those created later (the last 50) procedures

Results:

N=107 with p-AVFs (Ellipsys system) created May 2017-May 2018

N=107 consecutive patients underwent s-AVF creation during the same time period

- N=48 elbow s-AVFs
- N=59 wrist s-AVFs

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Results (continued):

Table 1: Baseline characteristics in percutaneous AVF cohort compared to surgical AVF cohort and subgroups

Characteristic	p-AVF (Ellipsys system) (N=107)	Comparison to Surgical AVF		Comparison to Elbow s-AVF subgroup		Comparison to Wrist s-AVF subgroup	
		(N=107)	P value*	(N=47)	P value*	(N=60)	P value*
Age (years)	63.6±15.4	63.5±15.7	0.48	63.9±14.7	0.44	63.2±16.7	0.46
BMI (kg/m²)	27.2±5.8	26.8±6.0	0.47	26.5±5.4	0.28	27.1±5.6	0.35
Sex			0.88		0.62		0.83
Male	66 (61.7)	65 (60.8)	--	27 (57.4)	--	38 (63.3)	--
Female	41 (38.3)	42 (39.2)	--	20 (42.6)	--	22 (36.7)	--
Hypertension	99 (92.5)	102 (95.3)	0.39	45 (95.7)	0.45	57 (95.0)	0.54
Diabetes	66 (61.7)	52 (48.6)	0.07	23 (48.9)	0.14	29 (48.3)	0.94
Receiving Hemodialysis	65 (60.7)	50 (46.7)	<0.05	26 (55.3)	0.52	24 (40.0)	0.01

Data are mean ± SD or n (%) , *p-value is as compared to p-AVF cohort
BMI: body mass index, p-AVF: percutaneous arteriovenous fistula, s-AVF: surgical arteriovenous fistula

Table 2: Percutaneous AVF outcomes compared to surgical AVF cohort and subgroups

Outcome	p-AVF (Ellipsys system) (N=107)	Comparison to Surgical AVF		Comparison to Elbow s-AVF subgroup		Comparison to Wrist s-AVF subgroup	
		(N=107)	P value*	(N=47)	P value*	(N=60)	P value*
Maturation at 6 weeks	65%	50%	0.02	59.6%	.48	43.3%	0.005
Outcomes at 12 months							
Primary patency†	61%	86%	0.01	85%	0.02	86%	0.05
Secondary patency†	91%	90%	NS	86%	NS	93%	NS
Wound infection	0.9%	9%	0.005	17%	0.0001	9.3%	0.005
Intervention	53%	36%	0.013	44.7%	0.32	30%	0.004
Percutaneous	41%	4%	<0.001	4.3%	<0.001	3.3%	0.02
Surgical	12%	33%	<0.001	40.4%	<0.001	26.7%	<0.001
Outcomes at 24 months‡							
Primary patency†	55%	52%	NS	65%	NS	35%	NS
Secondary patency†	91%	88%	NS	83%	NS	93%	NS
High flow/ steal syndrome	0%	3.7%	NS	3.6%	NS	3.6%	NS
Aneurysm	0%	2.8%	NS	4.3%	NS	1.6%	NS
Intervention	70%	78%	0.21	91.5%	0.04	66.7%	0.64
Percutaneous	53%	42%	0.10	42.6%	0.22	41.7%	0.31
Surgical	17%	36%	0.002	48.9%	<0.001	25%	0.2

*p-value is as compared to p-AVF cohort
† Per Kaplan-Meier analysis
‡Includes data/events occurring from time of index intervention until 24 months, inclusive of events at 12 months
p-AVF: percutaneous arteriovenous fistula, s-AVF: surgical arteriovenous fistula

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Results (continued):

- Maturation rate at 6 weeks was higher for the p-AVFs (Ellipsys system) as compared to s-AVFs (65% vs. 50%, p=.02)
- At 12 months, the p-AVF cohort required more secondary percutaneous interventions as compared to the s-AVF cohort (41% vs 4%, p<.001), but fewer surgical interventions were required (12% vs. 33%, p<.001)
  - Interventions primarily included planned and staged superficialization for both groups
- At 24 months, the s-AVF and p-AVF cohorts required a similar proportion of percutaneous interventions (42%vs 53%; p=.1). However, the s-AVF cohort still required more surgical interventions (36% vs 17%; p=.01)
- Primary patency per Kaplan-Meier analysis was higher for the s-AVF cohort at 12 months (86% vs 61%, p<0.01), but not different at 24 months (52% vs 55%, p=.48) as compared to p-AVFs
- Secondary patency rates were similar at both 12 months (91% vs. 90%, p=NS) and 24 months (91% vs 88%, p=NS)

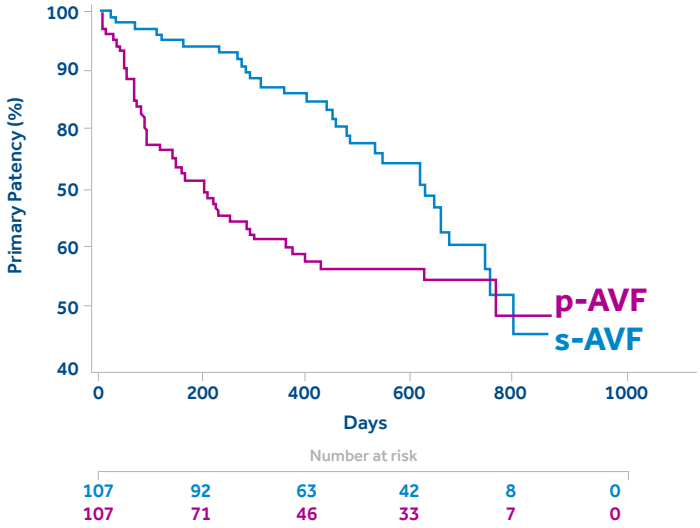

Figure 1: Primary patency

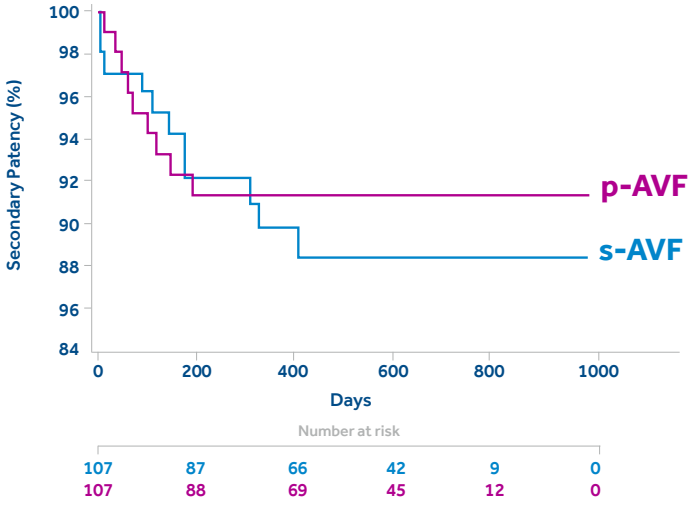

Figure 2: Secondary patency

- There were significantly fewer wound infections (0.9% vs. 9%, p=.005) and surgical interventions (12% vs. 33%, p<.001) in the p-AVF cohort as compared to the s-AVF cohort
- There was no occurrence of high flow/steal syndrome or aneurysmal degeneration in the p-AVF cohort; within the s-AVF cohort there were 3 cases of high-flow AVFs and 3 experienced aneursymal degradation (p=not significant)
- Kaplan-Meier curves comparing primary patency rates for the first 50 p-AVF procedures to the last 50 p-AVF procures were very similar, suggesting a minimal learning curve effect

Discussion:

- AVFs continue to have high primary and secondary failure rates, requiring subsequent interventions
- There was a more frequent need for percutaneous transluminal angioplasty after p-AVF, which lead to lower primary patency rates through 12 months compared to the s-AVF cohort; this may be due to the smaller anastomosis (4-5 mm) created with the Ellipsys system
- p-AVFs have better secondary outcomes (i.e., wound infection, steal syndrome, and aneurysm formation) as compared to s-AVFs
- The Ellipsys system is unique it that it requires only a single venous catheter puncture and ultrasound guidance to create a permanently fused anastomosis between the proximal radial artery and perforating vein of the elbow
  - Technique has a short learning curve and is appropriate to perform in an outpatient office procedure center
  - High patient satisfaction due to lack of scarring and a better esthetic result

Author's Conclusion:

Percutaneous fistulas created with the Ellipsys system had superior maturation rates and similar patency rates with s-AVFs; p-AVFs had lower risk of infection and surgical revision and better wound healing.

Funding Source:

Not funded by industry

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If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety and warning information. If you are located outside the United States, see the device manual for detailed information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

Ellipsys™ vascular access system
Brief statement

Indications for Use:
The Ellipsys™ system is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.

Contraindications
- The Ellipsys™ system is contraindicated for use in patients with target vessels that are <2 mm in diameter. The Ellipsys™ System is contraindicated for use in patients who have a distance between the target artery and vein > 1.5 mm

Warnings
- The Ellipsys™ system has only been studied for the creation of an AV fistula using the proximal radial artery and the adjacent perforating vein. It has not been studied in subjects who are candidates for surgical fistula creation at other locations, including sites distal to this location.
- The Ellipsys™ system is not intended to treat patients with significant vascular disease or calcification in the target vessels.
- The Ellipsys™ system has only been studied in subjects who had a patent palmar arch and no evidence of ulnar artery insufficiency.
- Use only with the Ellipsys™ Power Controller, Model No. AMI-1001.
- The Ellipsys™ Catheter has been designed to be used with the 6 F Terumo Glidesheath Slender™*. If using a different sheath, verify the catheter can be advanced through the sheath without resistance prior to use.
- Use ultrasound imaging to ensure proper placement of the catheter tip in the artery before retracting the sheath, since once the distal tip of the catheter has been advanced into the artery, it cannot be easily removed without creation of the anastomosis. If the distal tip is advanced into the artery at an improper location, complete the procedure and remove the catheter as indicated in the directions for use. It is recommended that a follow-up evaluation of the patient is performed using appropriate clinical standards of care for surgical fistulae to determine if any clinically significant flow develops that require further clinical action.

Precautions
- This product is sterilized by ethylene oxide gas.
- Additional procedures are expected to be required to increase and direct blood flow into the AVF target outflow vein and to maintain patency of the AVF. Care should be taken to proactively plan for any fistula maturation procedures when using the device.
- In the Ellipsys™ study, 99% of subjects required balloon dilatation (PTA) to increase flow to the optimal access vessel and 62% of subjects required embolization coil placement in competing veins to direct blood flow to the optimal access vessel. Prior to the procedure, care should be taken to assess the optimal access vessel for maturation, the additional procedures that may be required to successfully achieve maturation, and appropriate patient follow-up. Please refer to the "Arteriovenous Fistula (AVF) Maturation" section of the labeling for guidance about fistula flow, embolization coil placement, and other procedures to assist fistula maturation and maintenance.
- The Ellipsys™ system is intended to only be used by physicians trained in ultrasound guided percutaneous endovascular interventional techniques using appropriate clinical standards for care for fistula maintenance and maturation including balloon dilatation and coil embolization.
- Precautions to prevent or reduce acute or longer-term clotting potential should be considered. Physician experience and discretion will determine the appropriate anticoagulant/antiplatelet therapy for each patient using appropriate clinical standards of care.

Potential Adverse Effects
Potential complications that may be associated with creation and maintenance of an arteriovenous fistula include, but may not be limited to, the following:
- Total occlusion, partial occlusion or stenosis of the anastomosis or adjacent outflow vein
- Stenosis of the central AVF outflow requiring treatment per the treatment center's standard of care
- Failure to achieve fistula maturation
- Incomplete vessel ligation when using embolization coil to direct flow
- Steal Syndrome
- Hematoma
- Infection or other complications
- Need for vessel superficialization or other maturation assistance procedures.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important Information: Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

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