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Original Article

ORIGINAL ARTICLE

Comparative outcomes of surgical versus percutaneous arteriovenous fistulas: a prospective study

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ABSTRACT

Background. For patients undergoing haemodialysis (HD), the choice of vascular access is pivotal in determining morbidity and mortality outcomes. Traditionally, native arteriovenous fistulas (AVFs) have been created through surgical procedures. However, percutaneous endovascular devices for AVF formation have been introduced into clinical practice, showing promising early results. This study aims to compare the outcomes of endovascular AVFs (endoAVFs) created using the WavelinQ EndoAVF System (BD, Franklin Lakes, NJ, USA) and surgically created radiocephalic (RC) AVFs in real-world settings.

Methods. This prospective, single-centre, two-arm study included patients who underwent the creation of either an endoAVF using the WavelinQ EndoAVF System or an RC AVF at a university hospital between December 2021 and August 2023.

Results. A total of 20 patients who underwent an endoAVF and 40 who underwent a surgical AVF (SAVF) were included. Technical success was 100% in both groups. A total of 75% of the endoAVFs and 60% of the SAVFs met the criteria for physiological suitability. Among the AVFs that reached physiological suitability, the cannulation rate was 66% for the endoAVFs and 70.86% for the SAVFs. At the 6-month follow-up, the primary and cumulative patency rates were 65% and 75% in the endoAVF group and 57.5% and 60% in the SAVF group, respectively. At 12 months, these rates were 50% and 70% in the endoAVF group and 50% and 60% in the SAVF group, respectively. No serious adverse events were observed. The reintervention rate was 0.25/patient/year in the endoAVF group and 0.1 in the SAVF group.

Conclusion. The results of our study showed endoAVFs may be a safe and effective alternative to RC AVFs, showing high rates of technical success and patency with a low rate of reinterventions and complications.

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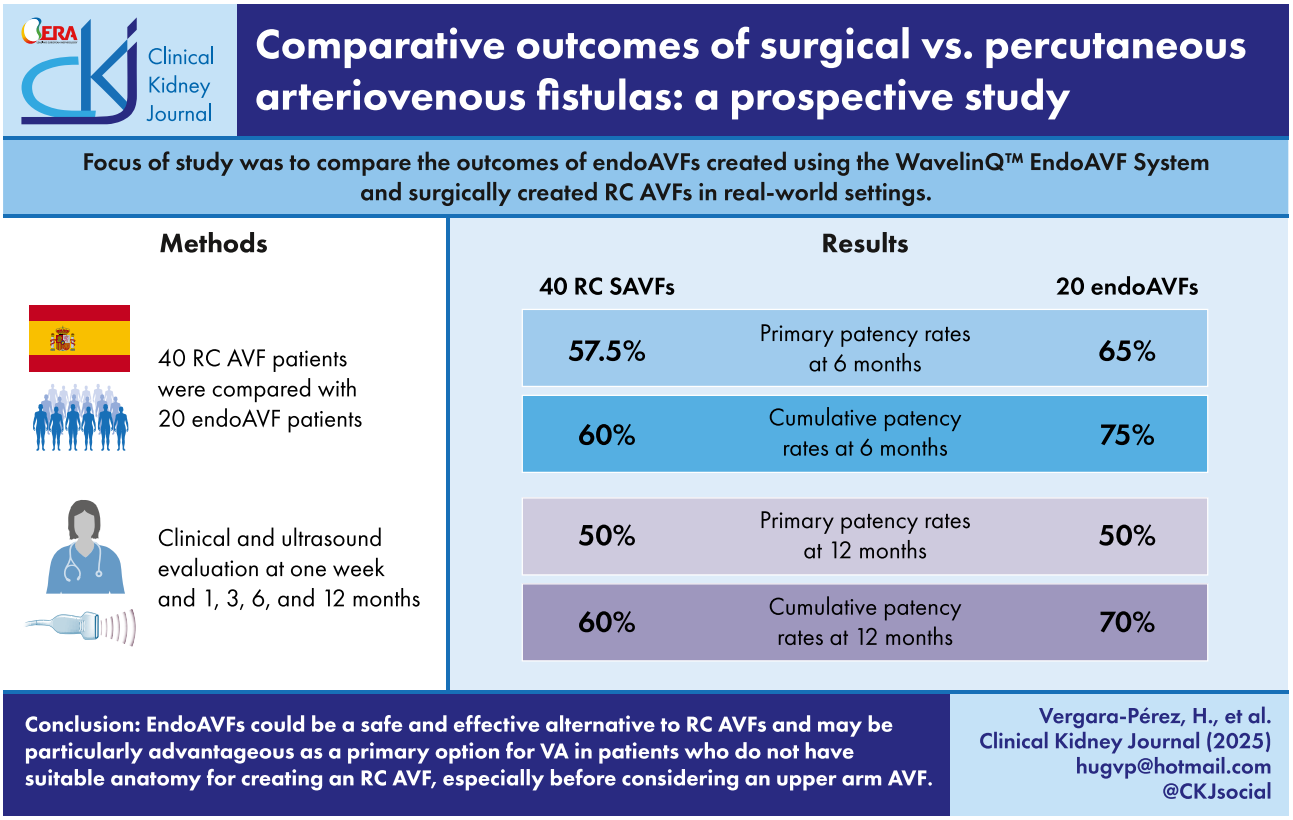
GRAPHICAL ABSTRACT



Keywords: arteriovenous fistula, haemodialysis, percutaneous AVF, surgical AVF, vascular access

KEY LEARNING POINTS

What was known:

- Despite evidence of the benefits of using new minimally invasive systems for creating arteriovenous fistulas (AVFs), very few studies directly compare these endovascular AVFs (endoAVFs) with classic surgical AVFs, making it difficult to consider them a real alternative for AVFs in haemodialysis patients.

This study adds:

- This study is the first to compare patients with surgically and endovascularly prospectively created AVFs. This enables the assessment of patency and intervention rates and the progression of brachial artery flow and drainage vein diameter.

Potential impact:

- EndoAVFs could be a safe and effective alternative to radiocephalic (RC) AVFs, showing high rates of technical success and patency with a low rate of reinterventions and complications.
- EndoAVFs may be particularly advantageous as a primary option for vascular access in patients who do not have suitable anatomy for creating an RC AVF, especially before proceeding with an AVF in the upper arm.

INTRODUCTION

For patients undergoing haemodialysis (HD), vascular access is a crucial aspect that affects both their morbidity and mortality [1, 2]. There are different types of vascular access. However, following clinical guidelines, native arteriovenous fistulas (AVFs) remain the first option to consider when a patient begins HD, due to their lower complication rates and greater long-term patency [3, 4]. These AVFs have been created using a surgical technique first performed in 1966 by Kenneth C. Appell [5].

When creating an AVF, it is important to individualize the procedure based on each patient; however, these AVFs are generally placed as distally as possible to preserve the maximum segment of puncturable veins and maintain vascular anatomy for potential future access if needed [6, 7]. These distal AVFs have

Table 1: Inclusion and exclusion criteria.

Inclusion criteria:
- Patients ≥18 years of age.
- Established and irreversible end-stage renal disease requiring HD (including patients with CKD stage 5 non-dialysis dependent).
- Obtained written informed consent.
- Absence of clinically significant diseases that could compromise the procedure in the 30 days prior.
- For the performance of an endoAVF, patients who are not candidates for or rejected the creation of an SAVF, or those who had previously undergone one but experienced primary or secondary failure, have been included.
- Meet the following anatomical criteria by ultrasound: target vein and artery size ≥2 mm, permeable proximal drainage veins and compressible proximal radial/cubital artery with no intimal calcifications.

Exclusion criteria:
- Patients refused to sign the written informed consent.
- Patients with cognitive impairment or whose mental condition hindered understanding of the information in the informed consent.
- Evidence of active infections at the time of the procedure.
- Patients with severe diastolic dysfunction whose manifestations could be affected by the performance of an AVF.

low complication rates and high patency rates; however, they can have a high primary failure rate, which can range between 10% and 30% and can even reach 50% in certain patient groups [8–11], along with a high maturation failure rate, with up to 30% of AVFs not maturing sufficiently within the 3 months following their creation [10, 12, 13].

In 2018, the US Food and Drug Administration (FDA) approved two new endovascular systems for creating native AVFs using minimally invasive methods. These systems are the WavelinQ EndoAVF System (BD, Franklin Lakes, NJ, USA) and the Ellipsys EndoAVF System (Medtronic, Dublin, Ireland) [4, 14]. Numerous publications have demonstrated the benefits of using these minimally invasive systems, showing low complication rates, high patency and a low rate of reinterventions [15–25].

This study compared the outcomes of endovascular AVFs (endoAVFs) created using the WavelinQ EndoAVF System and surgically created radiocephalic (RC) AVFs in real-world settings. The primary objectives were to compare the technical success rate, efficacy and cannulation rates. The secondary objectives included comparing primary and cumulative patency, safety and the number of procedures required to maintain fistula patency.

MATERIALS AND METHODS

Study design

This prospective, single-centre, two-arm study included patients who underwent the creation of either an endoAVF using the WavelinQ EndoAVF System or an RC AVF at a university hospital between December 2021 and August 2023. The study received approval from the hospital's ethics committee and all patients provided written informed consent before undergoing the procedure.

Study population

Eligible patients for the study included adults with chronic kidney disease (CKD) stage 5 (dialysis dependent or non-dialysis dependent) who underwent a procedure for the creation of an AVF, either surgical or endovascular. A formal sample size calculation was not performed due to the exploratory nature of this study.

The complete inclusion and exclusion criteria for the study can be found in Table 1.

The selection criteria were designed to ensure a representative sample of the CKD population requiring AVF creation while minimizing confounding factors. Specific inclusion criteria focused on patients with a clinical indication for AVF creation. In contrast, exclusion criteria targeted those with comorbidities or anatomical considerations that could compromise the safety or success of AVF formation. This approach allowed for a robust comparison of the surgical and endovascular methods under real-world conditions, thereby enhancing the external validity of the findings.

Intimal vascular calcification, a recognized contraindication to endoAVF creation, was assessed preoperatively using Doppler ultrasound. Compressibility of the radial or cubital artery was evaluated as a proxy for the absence of significant calcifications. Arteries that could not be adequately compressed during ultrasound examination were excluded from the study.

Device characteristics and procedural characteristics

The WavelinQ EndoAVF System that was used to perform endoAVFs consists of two 4 French (4F) magnetic catheters. The venous catheter contains a radiofrequency (RF) electrode connected via an electrocautery pencil to an electrocautery unit that delivers RF energy. Conversely, the arterial catheter contains a ceramic stop that receives the electrode once both catheters are attracted. Both catheters have rotational indicators to ensure they are in the correct position [18].

Before the intervention, an ultrasound study was conducted to ensure the suitability of each patient for endoAVF creation and to study the site of catheter access and AVF creation. The procedure was then performed with regional anaesthesia of the upper limb, following the steps described in previous publications [17, 26]. At the end of the procedure and after removing both catheters, a fistulography was performed to verify the technical success of the procedure. Additionally, ultrasound was used to measure the flow of the brachial artery for later reference.

The RC AVFs were created using the standard technique by vascular surgeons [27]. This involves making an incision at the wrist to expose the radial artery and cephalic vein, following preoperative vascular mapping to confirm suitability. Under local anaesthesia, the cephalic vein is transected and connected to the radial artery via an end-to-side anastomosis using fine sutures. After completing the anastomosis, patency is confirmed by checking for a palpable thrill and audible bruit, ensuring adequate blood flow. The incision is then closed.

All procedures were performed by three interventional radiologists and two vascular surgeons. The radiologists had varying levels of experience with endoAVF creation, ranging

from 1 to 3 years, as the procedure was newly adopted in our centre. In contrast, the vascular surgeons had >10 years of experience with surgical AVF (SAVF) creation. This discrepancy in experience may have influenced the observed outcomes and highlights the potential impact of the learning curve for new techniques such as endoAVF.

Follow-up

After AVF creation, clinical and ultrasound monitoring was conducted at 1 week, 4 weeks and 3, 6 and 12 months. Clinically, the assessment included the maturation time of the AVF, the time to first use and the absence of complications. Ultrasound monitoring included the patency of the anastomosis, the flow of the brachial artery, the diameter of the vein, as well as the study of possible complications after the procedure, such as haematoma, fluid collection, aneurysm, pseudoaneurysm and stenosis.

Study definitions and outcome measures

Technical success was defined as flow visualization through the anastomosis using angiography immediately after the procedure. The primary efficacy endpoint was the percentage of AVFs that achieved physiological suitability; this criterion was met when the endoAVF demonstrated a brachial artery flow ≥500 ml/min and a venous diameter ≥5 mm, measured using Doppler ultrasound, or when successful cannulation with two needles for dialysis was performed. Primary failure was defined as access that has either no appearance or a loss of bruit or thrill within 72 hours of creation or access that, despite radiological or surgical intervention, cannot be used successfully for dialysis within 3 months following its creation. Standardized definitions were used for primary and cumulative patency [28]. Safety was defined as the number of serious adverse events directly related to the procedure that led to a significant deterioration in the patient's health, such as death, the need for medical intervention or hospitalization.

Statistical analysis

For statistical analysis, SPSS Statistics version 29.0.1.0 (IBM, Armonk, NY, USA) was used. Continuous variables were reported based on distribution, as mean and standard deviation (SD) or median and interquartile range (IQR). Categorical variables were reported as counts and percentages. Categorical variables were compared using Pearson's chi-squared test and quantitative variables were compared using Student's *t*-test if they followed a normal distribution or the Mann–Whitney U test if they did not follow a normal distribution. A P-value <.05 was considered statistically significant. An analysis of primary patency survival was conducted using the Kaplan–Meier method, which allowed us to estimate the patency rate over time, and statistical significance was calculated using a logrank test.

RESULTS

Patients who underwent AVF creation between December 2021 and August 2023 were included in this study. A total of 40 patients who underwent RC AVF creation and 20 who underwent endoAVF creation were included. The endoAVFs were created using the WavelinQ EndoAVF System by interventional radiologists, whereas vascular surgeons performed the RC AVFs. All patients were followed for 12 months.

Regarding the demographic characteristics of the patients, the mean age of the RC AVF group was 65.1 ± 8.5 years. In contrast, the endovascular AVF group had a mean age of 66.45 ± 13.41 years, with no statistically significant differences between the two groups ($P = .318$). A total of 90% (18/20) of the patients in the endoAVF group were men, compared with 72.5% (29/40) in the SAVF group. The remaining baseline characteristics are presented in Table 2 and details about dialysis treatment are included in Table 3.

Regarding the CKD stage at the time of AVF creation, 30% (6/20) of the patients in the endoAVF group were in pre-dialysis, compared with 52.5% (21/40) of the patients in the SAVF group. In the endoAVF group, 70% (14/20) of the patients were on HD using a central venous catheter (CVC), while 45% (18/40) of the patients in the SAVF group were on HD using a CVC. Notably, one patient in the SAVF group was undergoing peritoneal dialysis when the AVF was created, subsequently transitioning to HD once the AVF became physiologically suitability. Of the patients who underwent SAVF, 12.5% (5/20) had a previous AVF. In the group of patients with an endoAVF, 40% (8/40) had a history of a failed previous AVF, which indicates a statistically significant difference between the groups ($P = .015$). It is important to note that 100% of the previous AVFs in the SAVF group were RC AVFs in the opposite limb. In contrast, in the endoAVF group, six were RC AVFs in the same limb as the endoAVF and two were RC AVFs in the opposite limb.

In the creation of AVFs, surgical and endovascular procedures achieved a 100% technical success rate, with no occurrence of serious adverse events.

During the ultrasound evaluation within the first 90 days following the procedure, 25% (5/20) of the endoAVFs and 40% (16/40) of the SAVFs did not achieve physiological suitability and were not eligible for repair, thus being classified as a primary failure ($P = .251$). The difference in maturation rates was not statistically significant ($P = .390$).

Among those AVFs that achieved physiological suitability, successful cannulation with two needles was accomplished in 66.6% (10/15) of the endoAVFs and 70.83% (17/24) of the SAVFs. Among the five patients with endoAVFs who achieved physiological suitability but were not cannulated, four patients had non-dialysis-dependent CKD and one was transplanted during follow-up. In the group of SAVFs, all patients whose AVFs reached physiological suitability but were not cannulated were in a state of non-dialysis-dependent CKD (Fig. 1). Cannulation for HD was performed in 70% (7/10) in the cephalic vein and 30% (3/10) in the cephalic and median cubital/basilic veins in the endoAVF group. In contrast, 100% (17/17) of the cannulations in the SAVF group were performed using the cephalic vein. The progression of blood flow in the brachial artery and changes in the diameters of the drainage veins are summarized in Table 4. After analysing the results, we observed a statistically significant difference in the cephalic vein size between both groups at 1 week, 1 month and 1 year of follow-up. Regarding the brachial artery flow, we saw statistically significant differences in the first 3 months of follow-up.

At 6 months of follow-up, the primary and cumulative patency rates were 65% and 75% in the endoAVF group and 57.5% and 60% in the SAVF group, respectively. At 12 months, the primary and cumulative patency rates were 50% and 70% in the endoAVF group and 50% and 60% in the SAVF group, respectively (Fig. 2). There were no statistically significant differences observed in primary patency at 6 months ($P = .891$) or 12 months ($P = .968$). Similarly, cumulative patency showed no significant differences at either 6 months ($P = .908$) or 12 months ($P = .949$).

Table 2: Baseline characteristics of the cohort.

Characteristics	EndoAVFs	SAVFs	*P*-value
Age (years), mean ± SD	65.1 ± 8.5	66.45 ± 13.41	.318
Gender (male), *n* (%)	18 (90)	29 (72.5)	.186
Medical history, *n* (%)			
Smoker	6 (30)	10 (25)	.76
Hypertension	18 (90)	37 (92.5)	.545
Diabetes mellitus	13 (65)	18 (45)	.117
History of neoplasms	4 (20)	11 (27.5)	.753
Congestive heart failure	2 (10)	8 (20)	.471
Body mass index, mean ± SD	31.48 ± 8.7	29.63 ± 5.17	.206
Cause of ESKD, *n* (%)			
Diabetes mellitus	7 (35)	11 (27.5)	.550
Urological cause	4 (20)	5 (12.5)	.443
IgA nephropathy	1 (5)	0 (0)	.154
Polycystic kidney disease	1 (5)	3 (7.5)	.714
Vascular kidney disease	1 (5)	2 (5)	1.00
Cardiorenal syndrome	1 (5)	3 (7.5)	.714
Chronic hepatitis C–related cryoglobulinaemia	1 (5)	0 (0)	.154
Unknown	1 (5)	6 (15)	.255
Other	3 (15)	1 (2.5)	.067
CKD stage, *n* (%)			
HD	14 (70)	18 (45)	.067
Pre-dialysis	6 (30)	21 (52.5)	.168
Peritoneal dialysis		1 (2.5)	.476
History of another AVF, *n* (%)	8 (40)	5 (12.5)	.015

Table 3: Details about dialysis treatment.

Variable	SAVFs	EndoAVFs	*P*-value
Qb (ml/min)	427 ± 14.67	423.5 ± 16.33	.141
Arterial pressure (mmHg)	165 ± 5.67	151 ± 7.33	<.001
Venous pressure (mmHg)	−165 ± 7.8	−180 ± 5.2	<.001
Kt/V	1.43 ± 0.35	1,48 ± 0.21	.334
Convective dose (litres)	23.14 ± 1.45	22.5 ± 1.63	.141

This table compares key dialysis treatment parameters [blood flow (Qb), arterial and venous pressures (Kt/V) and convective dose] between SAVFs and endoAVFs. The statistical analysis was performed using the independent *t*-test for all variables (Qb, arterial and venous pressures, Kt/V and convective dose). Statistically significant differences were observed in arterial and venous pressures ($P < .001$), while no significant differences were found in the other parameters.

Throughout the year of follow-up, five procedures were performed in the endoAVF group to maintain patency, compared with four procedures performed in the SAVF group. In the endoAVF group, four angioplasties were performed due to decreased flow in the brachial artery and one embolization of the brachial veins was carried out to redirect the blood flow. In the SAVF group, two juxta-anastomotic angioplasties and two cephalic vein thrombectomies were performed. Additionally, a late thrombosis occurred in the endoAVF group, which was not eligible for repair, leading to the loss of vascular access. Consequently, the reintervention rate was 0.25/patient/year in the endoAVF group and 0.1/patient/year in the SAVF group ($P = .043$).

DISCUSSION

Our results demonstrate the viability of endoAVF as an effective alternative to SAVF in HD patients. Both procedures achieved a 100% technical success rate, with no serious adverse events, demonstrating the safety of both techniques. Although the maturation rate of the endoAVFs did not show statistically significant differences compared with the SAVFs, there was a lower primary failure rate and a higher percentage of patients in the endoAVF group achieved physiological suitability. At 6 months, the primary and cumulative patency rates were higher in the endoAVF group (65% and 75%) compared with the SAVF group (57.5% and 60%). Additionally, in the endoAVF group, there was a greater increase in brachial artery flow and a larger increase in the diameter of the drainage veins compared with the SAVF group.

Technical success was achieved in 100% of our patients in both the endoAVF group and the SAVF group. This result is consistent with findings previously reported in the literature, where most studies reported technical success rates >96% [15, 16, 18–20, 26, 29, 30].

Our findings reinforce the reliability of both techniques, suggesting a high level of consistency in achieving successful vascular access creation across different settings and patient populations.

During the first 90 days after the procedure, 75% (15/20) of the endoAVFs and 60% (24/40) of the SAVFs achieved physiological suitability, while the remainder were considered primary AVF failures. The high primary failure rate observed in the SAVF group is similar to those reported by other studies, where a primary failure rate ranging from 10% to 60% has been observed in distal AVFs [8–11, 31–34]. Regarding endoAVFs, these results also align with data published in different studies and analysed data from 120 patients from three different studies [the everlinQ Endovascular Access System Enhancements Study (EASY study), the EASE-2 study and the everlinQ EndoAVF EU study] who underwent endoAVF using the WavelinQ 4F EndoAVF System, reporting a physiological suitability rate of 80.2% at 3 months. In their prospective comparison of 30 endoAVFs with 30 surgical AVFs, Inston *et al.* [19] reported a physiological suitability rate

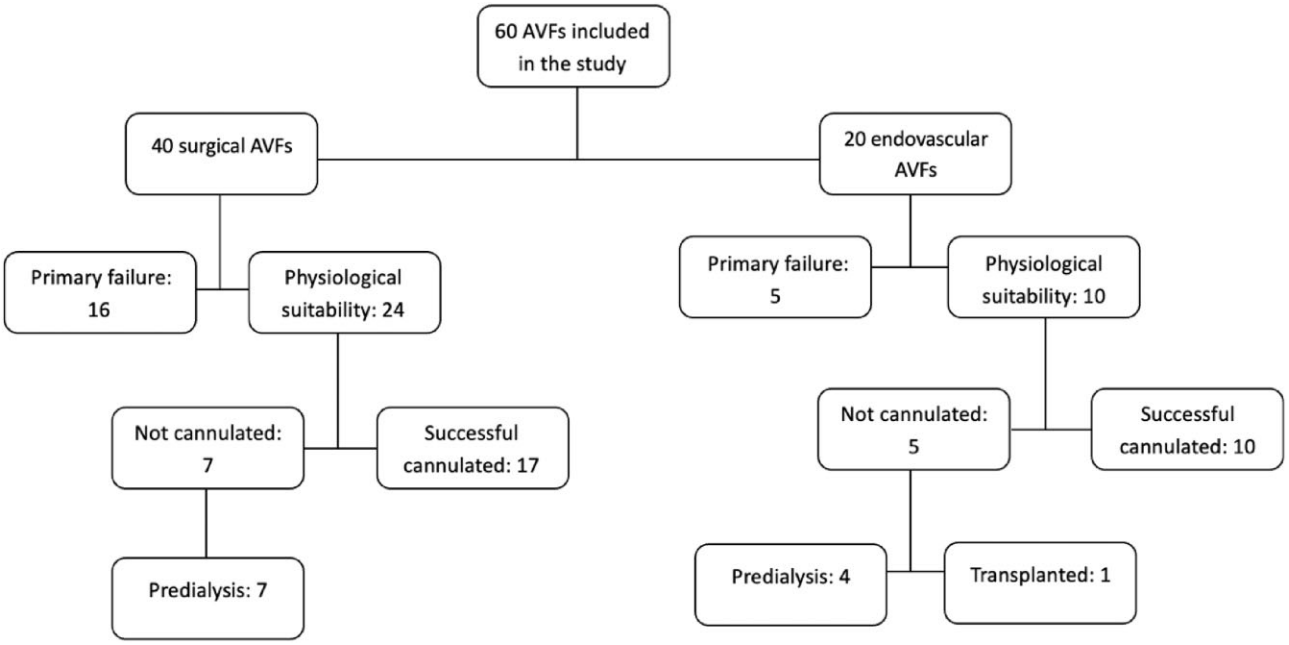


Figure 1: AVFs across groups: conducted punctures and justifications for non-intervention.

Table 4: Flows in the brachial artery and diameter of the vein throughout the follow-up.

Type	Previous	1 week	1 month	3 months	6 months	1 year
EndoAVFs: cephalic vein diameter (mm)	4.35 ± 1.05	5.60 ± 1.22	6.05 ± 1.15	6.16 ± 0.93	6.9 ± 2.12	6.8 ± 0.43
SAVFs: cephalic vein diameter (mm)	2 ± 1.45	4.67 ± 1.75	5.31 ± 1.36	5.63 ± 1.48	6.07 ± 0.58	6.45 ± 0.404
P-value: cephalic diameter (mm)		.02	.031	.096	.091	.046
EndoAVFs: basilic vein diameter (mm)	4.1 ± 1.06	5.4 ± 1.75	7.1 ± 1.54	7.28 ± 1.26	6.97 ± 1.45	7.15 ± 1.6
EndoAVFs: flow (ml/min)		592 (655)	905 (702)	760 (839)	878 (1244)	668 (931)
SAVFs: flow (ml/min)		500 (255)	550 (243)	620 (243)	650 (151)	700 (183)
P-value (flow)		.042	.06	<.001	.085	.921

The sizes of the draining veins are presented as mean ± SD and the flows of the brachial artery as median and IQR.

of 74.4% for the endoAVFs. Shahverdyan *et al.* [35], in their retrospective study comparing 100 patients with endoAVF (65 patients with an endoAVF performed using the Ellipsys System and 35 with the WavelinQ 4F EndoAVF System), reported a physiological suitability rate of 54.3% at 4 weeks and 71.4% throughout the rest of the WavelinQ group study. Both Lok *et al.* [26] and Kitrou *et al.* [18] report a physiological suitability rate of 87% for the performed endoAVFs, similar to the 88% reported by Zemela *et al.* [15].

Overall, the results for endoAVFs in our study are consistent with those previously published, indicating promising outcomes for this approach. Despite slight variations across different studies, the physiological suitability rates consistently point towards reliable and effective performance of endoAVFs, underscoring their potential as viable alternatives to surgical AVFs in appropriate patient populations.

Of those AVFs that achieved physiological suitability, 66.6% (10/15) of the endoAVFs and 70.83% (17/24) of the SAVFs were successfully cannulated. However, it is important to consider the higher primary failure rate in the SAVF group, so when considering this group, the cannulation rate is higher in the endoAVFs. These results regarding the cannulation rate of the endoAVF group are slightly lower than those previously reported in the literature, where some studies have reported cannulation rates >75%. In this context, it is interesting to mention the FLEX study, where Rajan *et al.* [36] reported a 96% (27/28) successful cannulation rate for the endoAVFs performed. In a study by Radosa *et al.* [20], successful cannulation was achieved in 100% of the patients. However, it is important to note that the number of patients included in the study was only eight. Berland *et al.* [29] reported a successful cannulation rate of 78% for patients on dialysis or who started during follow-up.

It should be noted that the lower rate of physiological suitability and successful cannulation compared with other studies may be due to patient selection for inclusion in the studies, as 40% (8/20) of the patients who underwent an endoAVF in our study had a prior failed AVF, which could indicate worse suitability for creating a new AVF. Additionally, this study includes the learning curve of interventional radiologists, which could explain the higher primary failure rate compared with other studies.

At 6 months of follow-up, the primary and cumulative patency rates were 65% and 75% in the endoAVF group and 57.5% and 60% in the SAVF group, respectively. At 12 months, these rates were 50% and 70% in the endoAVF group and 50% and 60% in the SAVF group, respectively. These results are consistent with those previously reported in the literature. For example, Inston *et al.* [19], in their retrospective study comparing 30 endoAVFs

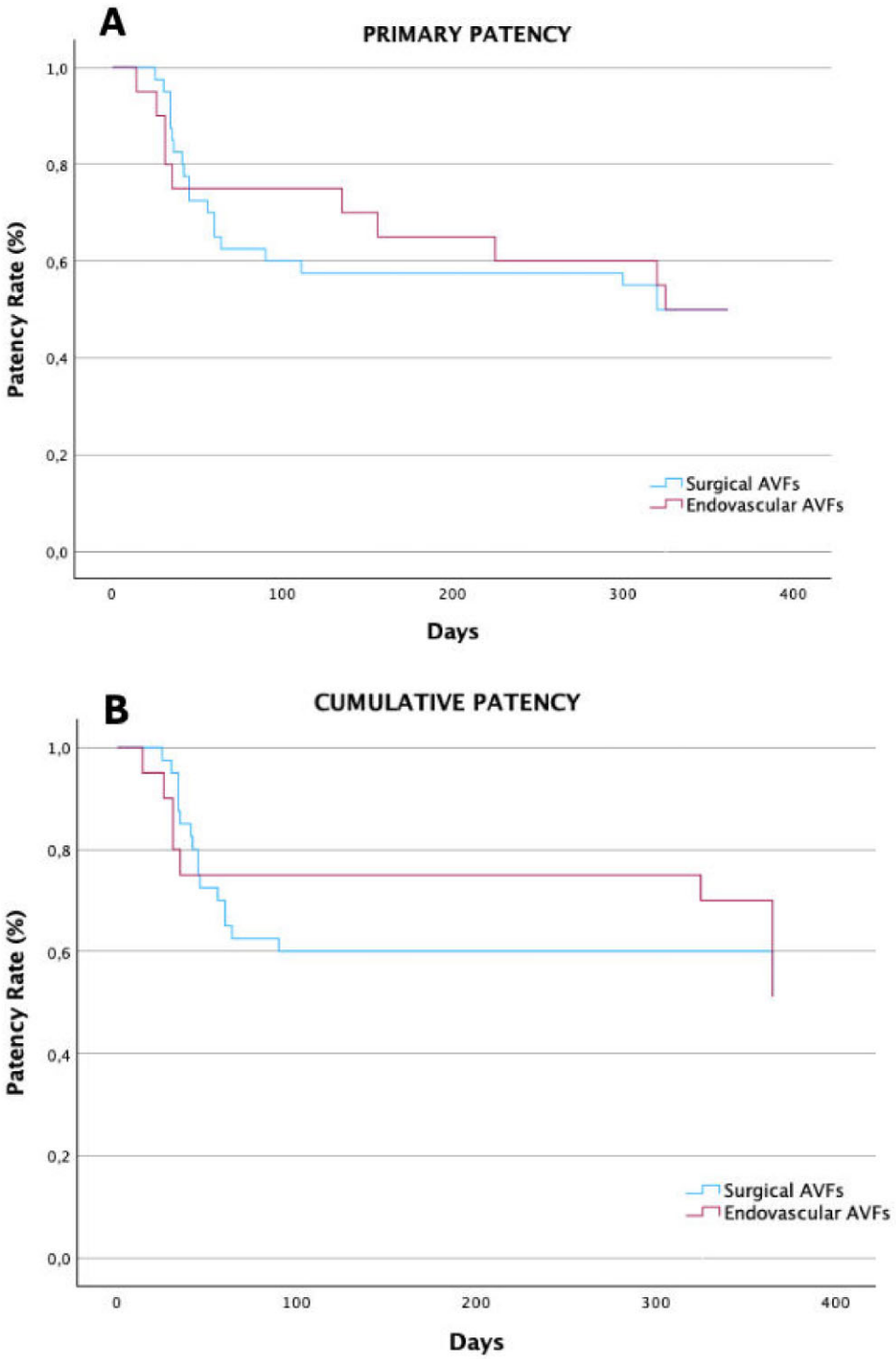


Figure 2: (A) Primary patency and **(B)** cumulative patency of surgical and endovascular AVFs throughout the follow-up.

performed using the WavelinQ 4F EndoAVF System with 40 RC AVFs, reported primary patency at 6 and 12 months of 65.5% and 56.5% for the endoAVF group and 53.4% and 44% for the RC AVF group, respectively. Similarly, they reported cumulative patency at 6 and 12 months of 75.8% and 69.5% for the endoAVF group and 66.7% and 57.6% for the RC AVF group, respectively. Regarding the patency rates of the RC AVF group, Al-Jaishi *et al.* [34] published a systematic review and meta-analysis that included 46 studies reporting patency rates similar to those of our SAVF group. For AVFs created in the lower arm, the primary and cumulative patencies at 1 year were 55% and 68%, respectively. In the Novel Endovascular Access Trial, Lok *et al.* [26] described higher patency than was obtained in our research, with primary and cumulative patencies at 12 months of 69% and 84%. Similarly, Berland *et al.* [29] and Radosa *et al.* [20] reported primary and cumulative patencies at 6 months of 71.9%, 87.8%, 86% and 100%.

In contrast to prior studies, Shahverdyan *et al.* [35] reported low patency rates for AVFs created with the WavelinQ 4F EndoAVF system, with primary and cumulative patencies of 33% and 60%, respectively.

Regardless of the type of system used for the creation of endoAVF, data from different studies comparing them with various types of SAVFs, whether RC, brachiocephalic or proximal forearm Gracz type, have shown clinical outcomes and patency rates that are equivalent or even superior in the endoAVF group [16, 19, 24, 25, 37]. Likewise, it has been noted that despite prior reports of lower costs, our findings suggest higher costs due to more frequent reinterventions compared with surgically created AVFs [37].

After the procedure and throughout the follow-up, five procedures were performed in the endoAVF group and four procedures in the SAVF group to maintain the patency of the AVFs. In the endoAVF group, four angioplasties were performed due to a decrease in flow in the brachial artery, and embolization of the brachial veins was carried out to redirect the flow. In the SAVF group, two juxta-anastomotic angioplasties and two thrombectomies of the cephalic vein were performed. Additionally, a late thrombosis occurred in the endoAVF group, which was not amenable to repair, leading to the loss of vascular access. Considering all patients, the reintervention rate was 0.25/patient/year in the endoAVF group and 0.1 in the SFAV group. Compared with other studies, the lower intervention rate in our study to maintain patency is noteworthy. For example, Inston *et al.* [19] report an intervention rate of 0.402 in the endoAVF group and 0.273 in the RC AVF group. The NEAT study [26] and the study published by Berland *et al.* [29] report a rate of 0.46 and 0.55 procedures/patient/year, respectively. Klein *et al.* [38], in a recently published multicentre study, report a rate of 0.73 procedures/patient/year. Compared with other studies of RC AVFs, Heindel *et al.* [39] reported a rate of 1.04 procedures/patient/year. Our results, compared with other cohorts, could be explained by the smaller number of patients in our study as well as the higher rate of primary failure in both groups.

This study has several limitations to consider. First, the sample size is small and the follow-up time is short, which prevents conclusions about long-term patency. This study also includes the learning curve of the interventional radiologists who, despite being familiar with forearm anatomy through ultrasound and angiography, were not experienced in creating AVFs or in using the device itself. Additionally, patients in the endoAVF group had a higher percentage of a history of failed AVFs, which could introduce a selection bias, as these patients may have been less likely to achieve physiological maturity due to their vascular condition. Finally, not all patients included in the study required HD during the follow-up period, which could imply a lower rate of complications associated with repeated cannulation of the AVF.

A randomized study design would have been ideal to minimize selection bias and provide a higher level of evidence. However, the practical challenges, including patient preferences, ethical considerations and the availability of experienced operators for each technique, precluded randomization in this pilot study. Instead, we aimed to provide real-world insights by comparing outcomes based on a prospective cohort design. Future studies should aim to incorporate randomization to strengthen the evidence base.

Almost 80% of the patients in the study were male, which is important because gender differences can influence vascular access outcomes in HD patients. Recent research has shown that gender affects both vascular access selection and clinical outcomes, with notable disparities in success rates and complications between males and females. These findings may help explain variations observed in our cohort [40]. Future studies should consider gender-related factors when evaluating the effectiveness and suitability of different vascular access strategies, including endoAVFs.

In conclusion, based on our experience, endoAVFs may be a safe and effective alternative to RC AVFs, showing high rates of technical success and patency with a low rate of reinterventions and complications. EndoAVFs may be particularly advantageous as a first option for vascular access in patients who do not have suitable anatomy for creating an RC AVF, especially before proceeding with an AVF in the upper arm. Nevertheless, despite the evidence regarding the viability of these endoAVFs, further prospective studies involving larger patient cohorts and extended follow-up periods are needed to validate these findings and determine if endoAVFs can be universally recommended as the first-line choice for vascular access.

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Written informed consent was obtained from all the participants before undergoing the procedure. The study received approval (on 20 June 2022) from the Research Ethics Committee of the General Hospital of Castellón, Avenida de Benicàssim, Castellón, Spain. The study was conducted according to the Declaration of Helsinki, the International Council for Harmonization Guidelines for Good Clinical Practice and applicable local regulations.

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AUTHORS' CONTRIBUTIONS

H.V. was responsible for the study design, data collection and interpretation and manuscript writing. J.R. was responsible for the study design, supervision and final manuscript review. P.B. and R.P.P. were responsible for the study design and supervision. A.R.P and A.G.B. were responsible for data collection. A.P.A. was responsible for statistical analysis and data interpretation. R.D.L was responsible for technical procedures and data collection.

DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this article. Further inquiries can be directed to the corresponding author.

CONFLICT OF INTEREST STATEMENT

None declared.

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