



Endovascular Versus Surgical Arteriovenous Fistulas: A Systematic Review and Meta-analysis

Muhammad Hammad Malik, Marwa Mohammed, David F. Kallmes, and Sanjay Misra

Rationale & Objective: To facilitate the process of dialysis for patients with kidney failure, an arteriovenous fistula (AVF) is created using either a surgical or percutaneous approach. We sought to compare the efficacy and procedural outcomes in creating an AVF percutaneously using Ellipsys (Avenu Medical) or WavelinQ (Becton Dickinson Medical) with surgery in all patients with kidney failure requiring a permanent AVF for dialysis.

Study Design: Systematic review and meta-analysis.

Setting & Study Populations: All patients requiring a permanent AVF for dialysis.

Selection Criteria for Studies: We included studies that compared either the Ellipsys device or WavelinQ directly with surgery to create an AVF for long-term dialysis.

Data Extraction: Two reviewers independently reviewed the studies and extracted the data. Conflicts were resolved with a discussion and approval from the senior author.

Analytical Approach: Fixed-effects or random-effects models were used to pool the fixed sizes and 95% CIs based on the level of heterogeneity.

Results: There was no statistically significant difference observed between surgical AVF and endovascular AVF when comparing the primary outcomes of procedural success (OR = 1.44; 95%

CI, 0.35, 5.88; $P = 0.61$; $I^2 = 0\%$), complications (OR = 0.28; 95% CI, 0.06, 1.46; $P = 0.13$; $I^2 = 69\%$), and the secondary outcomes of interest that included follow-up time (mean difference [MD] = -17.71; 95% CI, -189.53, 154.12; $P = 0.84$; $I^2 = 94\%$), failure rate (OR = 1.03; 95% CI, 0.21, 5.13; $P = 0.97$; $I^2 = 85\%$), and time to 2-needle cannulation (MD = -5.40; 95% CI, -38.88, 28.08; $P = 0.75$; $I^2 = 0\%$). However, a statistically significant difference was seen among the 2 groups for procedural time (MD = -54.25; 95% CI, -59.78, -48.71; $P < 0.001$; $I^2 = 98\%$), number of interventions needed to maintain patency (OR = 1.73; 95% CI, 1.22, 2.45; $P < 0.01$; $I^2 = 94\%$), and primary patency rate (OR = 0.34; 95% CI, 0.23, 0.52; $P < 0.001$; $I^2 = 0\%$).

Limitations: The total number of studies included in this review was limited, with 3 of the 4 included studies being retrospective and only 1 being prospective. There was a lack of heterogeneity and randomization.

Conclusions: Percutaneous fistula creation using Ellipsys or WavelinQ is a unique and safe alternative with outcomes comparable to surgery. Future studies are needed, including observational studies in current clinical practice, to evaluate the efficacy and outcomes of endovascular AVF creation in clinical populations.

Complete author and article information provided before references.

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Chronic kidney disease is one of the leading causes of mortality in the United States with all patients eventually requiring hemodialysis when medical management fails. To facilitate the process of dialysis, arteriovenous fistulas (AVFs) are created surgically at either the wrist or elbow for the management of patients with kidney failure.¹ It is preferred to have a peripheral AVF as it has better outcomes, a higher safety profile, and decreased complication rates than central catheters.^{2,3} However, surgically constructed fistulas are associated with significant downfalls such as short-term patency, infections, and maturation failure.^{4,5} Surgical fistulas also require further interventions to maintain normal function, be suitable for hemodialysis, and avoid complications.⁶ With modern advancements, we now have the technology to create AVFs effortlessly using a minimally invasive percutaneous approach in a short period of time.⁷ Currently, the 2 US Food and Drug Administration–approved devices available in the market are the Ellipsys Vascular Access System (Avenu Medical) and WavelinQ EndoAVF System (Becton Dickinson Medical). The Ellipsys device operates using

thermal anastomosis that allows the creation of an AVF,⁸ whereas the WavelinQ uses a dual catheter system containing magnets for appropriate alignment and creates an anastomosis between a deep artery and a vein using radiofrequency energy.⁹ This systematic review and meta-analysis aimed to directly compare the outcomes of endovascular AVF creation using these 2 devices with those of surgical AVF creation.

METHODS

Literature Search

This study was done in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines (Fig 1).¹⁰ A comprehensive search of several databases from 2014 to July 22, 2021, in the English language, was conducted. The databases included Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily, Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews, and Scopus. The

PLAIN-LANGUAGE SUMMARY

Arteriovenous fistulas (AVFs) are constructed either surgically or endovascularly using modern technology. This systematic review of the literature compares the efficacy of devices recently approved by the US Food and Drug Administration for endovascular fistula creation (Ellipsys and WavelinQ) with the historically popular surgical fistula. With regard to the primary outcomes of procedural success and number of complications, the devices were comparable to surgical AVF creation; however, only 4 studies met the search criteria. More studies are needed to evaluate the efficacy and outcomes of endovascular AVF creation in clinical populations.

search strategy was designed and conducted by an experienced librarian with input from the study's principal investigator. Controlled vocabulary supplemented with keywords was used to search for studies of endovascular AVFs using Ellipsys and WavelinQ in humans. The actual strategy listing all search terms used and how they were combined is available in [Item S1](#). Two studies included in the analysis were manually searched using the nested knowledge software.

Study Selection

Two reviewers (MHM, MM) independently screened the studies to match the inclusion criteria, and conflicts were resolved by discussion or in conjugation with a senior author. The first part of the study involved abstract and title screening, which was followed by full-text screening to establish inclusion. The inclusion criteria included any prospective or retrospective cohorts that compared either Ellipsys or WavelinQ device with surgery for the creation of an AVF. Studies were selected from 2014 onward and did not include animal subjects, literature reviews, laboratory studies, or conference abstracts. We excluded studies that only focused on either the Ellipsys or WavelinQ without comparing surgery or did not have sufficient data.

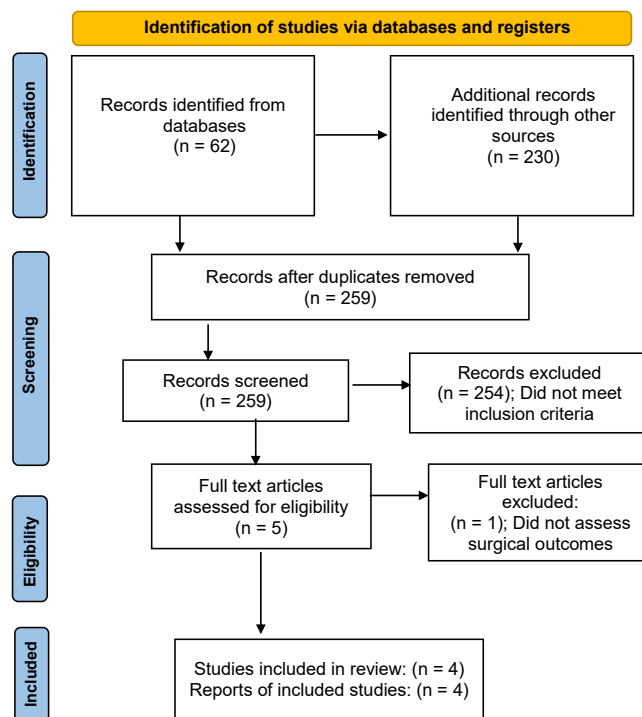


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analyses flowchart of study selection.

Outcomes of Interest and Data Extraction

All studies selected were reviewed, and all outcomes of the included studies were noted. The primary outcomes as included in our PROSPERO protocols were “procedural success” and “complications.” The reviewers also extracted the data regarding time to follow-up, primary and secondary patency, failure rate, time to 2-needle cannulation, procedural time, and the number of interventions needed after the procedure. Primary patency was defined as the patency from procedure up to the point at which intervention was needed to maintain patency. Secondary patency was defined as the period between access placement leading up to its abandonment.¹¹ Procedural success was defined as the completion of the procedure and

Table 1. Baseline Characteristics of Surgical Arteriovenous Fistula and Device Arteriovenous Fistula Groups

Outcomes	Number of Studies	Total Events	Odds Ratio (95% CI)	I ² Heterogeneity	P Value
Procedural success	3	Surgery, 173; device, 143	1.44 (0.35 to 5.88)	0	0.61
Complications	3	Surgery, 238; device, 220	0.28 (0.06 to 1.46)	69	0.13
Primary patency	3	Surgery, 199; device, 223	0.34 (0.23 to 0.52)	0	<0.01
Secondary patency	2	Surgery, 130; device, 133	0.91 (0.49 to 1.70)	0	0.77
Failure rate	3	Surgery, 171; device, 142	1.03 (0.21 to 5.13)	85	0.97
Further interventions	4	Surgery, 278; device, 249	1.73 (1.22 to 2.45)	94	<0.01
Procedural time	2	Surgery, 131; device, 113	-54.25 (-59.78 to -48.71)	98	<0.01
Time to 2-needle cannulation	2	Surgery, 90; device, 90	-5.40 (-38.88 to 28.08)	0	0.75
Follow-up time	3	Surgery, 171; device, 142	-17.71 (-189.53 to 154.12)	94	0.84

Abbreviation: CI, confidence interval.

Table 2. Outcomes for Surgical Arteriovenous Fistula and Device Arteriovenous Fistula

First Author, Year	Study Design	Device Type or Surgery	Age, y	Gender	BMI, kg/m ²	HTN	DM	Laterality	Follow-up, mo	Procedure Time, min
Inston, 2020	Prospective	WavelinQ	57 ± 15	Female, 5 (17%); male, 25 (83%)	N/A	N/A	N/A	L:R 23:7	16.6 ± 6.2	N/A
Inston, 2020	Prospective	Surgery	54 ± 17	Female, 11 (28%); male, 29 (72%)	N/A	N/A	N/A	L:R 25:15	15.6 ± 4.9	N/A
Harika, 2021	Retrospective	Ellipsys	63.6 ± 15.41	Female, 41 (38.3%); male, 66 (61.7%)	27.2 ± 5.78	99 (92.5%)	66 (61.7%)	L:R 28:29	24	N/A
Harika, 2021	Retrospective	Surgery	63.5 ± 15.69	Female, 42 (39.2%); male, 65 (60.8%)	26.8 ± 5.95	102 (95.3%)	52 (48.6%)	L:R 80:27	24	N/A
Shahverdyan, 2021	Retrospective	Ellipsys	66.0 ± (28.0-86.2)	Female, 31 (35%); male, 58 (51%)	26.2	N/A	32 (35.9%)	N/A	15.7 ± 16.9	14 (8-31)
Shahverdyan, 2021	Retrospective	Surgery	54 ± (33.2-87.7)	Female, 34 (49%); male, 35 (51%)	28.7	N/A	33 (47.8%)	N/A	8.9 ± 22.5	70 (45-128)
Osofsky, 2020	Retrospective	Ellipsys	56.7 ± 22.6	Female, 12 (50%); male, 12 (5%)	30.5 ± 6.7	21 (87.5%)	18 (75%)	L:R 15:8	6.1 ± 4.0	60 ± 40
Osofsky, 2020	Retrospective	Surgery	62.5 ± 13.2	Female, 30 (48%); male, 32 (52%)	28.8 ± 6.8	58 (93.5%)	46 (74.2%)	L:R 41:20	2.7 ± 2.6	56 ± 25

Abbreviations: BMI, body mass index; DM, diabetes mellitus; HTN, hypertension; L, left; N/A, not available; R, right.

construction of a fistula using either the endovascular approach or surgical approach. Complications were defined as any event that occurred during the procedure or during the period of follow-up and depending upon the authors' original findings may or may not include thrombosis, bleeding, aneurysm, or high output fistula. Fistula failure was defined as the abandonment of the fistula or those that failed to mature. Time to 2-needle cannulation was used as the sign of physiologic maturity and defined as the time from creation to needle cannulation for dialysis. Further interventions were defined as any procedure that was done after the successful construction of a fistula to maintain its patency and included transluminal angioplasty, coil embolization, operative ligation of the basilic or cephalic vein, and transposition of the basilic or cephalic veins.

Risk of Bias and Quality Assessment

Two reviewers (MHM, MM) used the Newcastle-Ottawa Scale¹² to assess the quality of included studies.

Statistical Analysis

The outcomes of interest that were present in more than one study underwent meta-analysis using Revman 5.0 software package.¹³ We presented dichotomous variables as an odds ratio (OR) with a 95% CI. For continuous variables, we used the mean difference with a 95% CI. The P value was set at P = 0.05 to detect statistical significance for fixed-effects and random-effects models.¹⁴ The random-effects model was used when significant heterogeneity was present, which was determined using the I² values.¹⁵ I² values of <50% were considered as low heterogeneity, and those of ≥50% were considered as high heterogeneity.

RESULTS

Search Results

We ran a librarian-assisted search and self-search using nested knowledge software. We found a total of 292 articles and were left with 259 after duplicates were removed. We screened the abstracts to include the ones that matched our criteria and exclude those that did not. We selected 5 articles for full-text screening that compared the device outcomes directly with surgery but found that 1 study did not mention the surgical outcomes completely and excluded it. In the end, 4 studies underwent qualitative and quantitative analysis (Fig 1).

Study Characteristics

We reviewed 4 studies (3 retrospective cohorts and 1 prospective cohort) with a total of 527 patients. Three studies focused on comparative outcomes between Ellipsys Vascular Access System and surgery¹⁶⁻¹⁸ and 1 focused on the WavelinQ EndoAVF System.¹⁹ The baseline characteristics are presented in Table 1, and the results of our studies are summarized in Table 2.

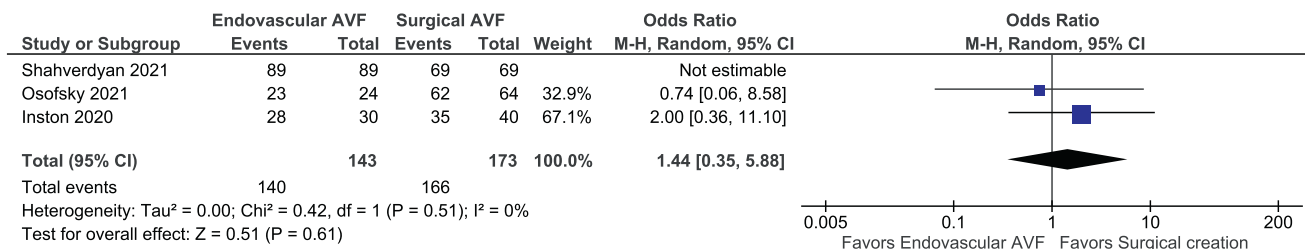


Figure 2. Meta-analysis of procedural success. Abbreviation: AVF, arteriovenous fistula; M-H, Mantel-Haenzsal.

Quality Assessment

We used the Newcastle-Ottawa Scale²⁰ to conduct a quality assessment of our selected articles. We reviewed the articles on the following parameters: the representativeness of exposed cohort, selection of nonexposed cohort, ascertainment of exposure, demonstration that outcome of interest was not present at the start of study, comparability of cohorts on the basis of design or analysis, assessment of outcome, follow-up length, and loss to follow-up. Most studies scored higher than 6; however, the study by Harika et al¹⁶ reported bias for comparability of cohorts, Osofsky et al¹⁸ reported bias due to patients lost to follow-up, and Shahverdyan et al¹⁷ reported bias due to the limited follow-up time of patients.

Outcomes

There was no statistically significant difference between the surgery group and the device group with similar results in the primary outcomes of procedural success (OR = 1.44; 95% CI, 0.35, 5.88; P = 0.61; I² = 0%) and complications (OR = 0.28; 95% CI, 0.06, 1.46; P = 0.13; I² = 69%). The secondary outcomes of interest that included follow-up time (mean difference = -17.71; 95% CI, -189.53, 154.12; P = 0.84; I² = 94%), failure rate (OR = 1.03; 95% CI, 0.21, 5.13; P = 0.97; I² = 85%), and time to 2-needle cannulation (mean difference = -5.40; 95% CI, -38.88, 28.08; P = 0.75; I² = 0%) also did not show any significant findings.

There was a statistically significant difference observed between the 2 groups for procedural time (mean difference = -54.25; 95% CI, -59.78, -48.71; P < 0.001; I² = 98%), which indicates that the device was able to

construct a fistula in a shorter period than surgery. The number of further interventions needed to maintain patency was significantly higher in the device group than in the surgery group (OR = 1.73; 95% CI, 1.22, 2.45; P < 0.01; I² = 94%). We also found that the initial primary patency was significantly higher for the surgery group in comparison to the device group (OR = 0.34; 95% CI, 0.23, 0.52; P < 0.001; I² = 0%); however, the outcomes were not statistically significant for secondary patency (OR = 0.91; 95% CI, 0.49, 1.70; P = 0.77; I² = 0%). The meta-analyses data are reported in Figs 2-10.

DISCUSSION

To our knowledge, this is the first systematic review to directly compare Ellipsys and WavelinQ with surgery for the creation of an AVF. The studies compared efficacy as well as overall safety in patients undergoing percutaneous fistula creation. Our study shows that the outcomes between surgical and percutaneous AVFs are similar with high success rates. The Ellipsys endovascular device uses a minimally invasive, ultrasound-guided approach to successfully create an anastomosis between 2 vessels with ease. It has been studied more frequently in the past^{21,22} and reported to have excellent overall outcomes. These studies also showed that fistulas created at the wrist level using Ellipsys perform better in long term owing to low flow volume and multiple venous outflow channels.²³ This leads to decreased hemodynamic complications such as high output heart failure and aneurysm formation, which are commonly seen when constructing elbow level fistulas.^{24,25} The WavelinQ system uses a bidirectional

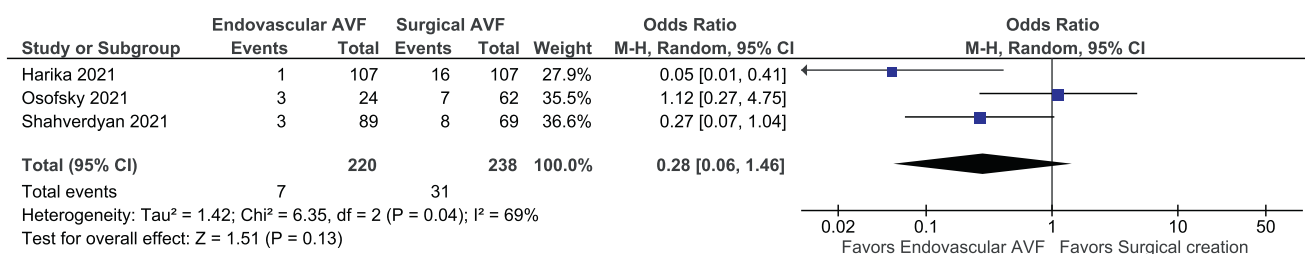


Figure 3. Meta-analysis of procedure complications. Abbreviation: AVF, arteriovenous fistula; M-H, Mantel-Haenzsal.

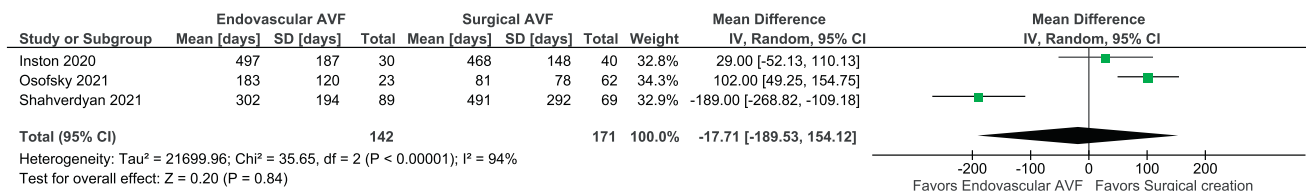


Figure 4. Meta-analysis of follow-up time. Abbreviations: AVF, arteriovenous fistula; IV, interval variable; SD, standard deviation.

approach with arterial access at the wrist and venous access at the elbow with successful outcomes superior to its surgical counterpart.^{9,26} WavelinQ uses the assistance of magnetic catheters and contrast angiography, thus allowing improved outcomes compared with Ellipsys, which uses ultrasound guidance only. However, the use of contrast for imaging guidance does carry a risk of adverse reactions and can be an important factor when considering the use of WavelinQ. Nonetheless, the ultimate deciding factor to proceed with percutaneous fistula creation is appropriate patient selection.

In our review, procedural success was not significantly different in either group, and both reported excellent outcomes. The procedural success and time for 2-needle cannulation, the sign of physiologic maturity, were similar in all reported studies. The average time for successful cannulation was 133 days for the device group and 138 days for the surgery group. Some studies have shown higher success in those who underwent surgical fistula creation as opposed to the endovascular approach, which may be due to the stricter requirements for a successful percutaneous AVF creation. In a systematic review of outcomes using Ellipsys and WavelinQ conducted by Wee et al,²⁷ it was found that patients should have an access target vessel of a minimum 2 mm in diameter with a perforator vein greater than 3 mm in size. To allow the anastomosis to be constructed appropriately, the artery and adjacent vein should have an approximate distance greater than 1.5 mm. These conditions may not always be met; however, it can be converted into a surgical fistula in patients with an urgent need for dialysis cannulation.

The difference in procedural success also depends on the experience level of the operator. Past studies have employed the services of experts from various departments such as

vascular surgery, interventional radiology, and nephrology to assist in the procedure. The option of having multiple specialists when performing a surgical fistula may not be possible in all hospitals; however, this may not be a problem for the Ellipsys or WavelinQ. A study conducted by Isaak et al²⁸ described the first virtual learning event completely teleproctored among first-time users of the Ellipsys device. This study showed the relatively short learning curve and the ability to reproduce favorable results within a short time of teaching. Not to mention the fact that the endovascular system allows for minimal scarring and short procedure times that are statistically significant compared with those with the surgery group. The average procedure time was between 30 and 40 minutes for experienced operators with safe outcomes and can be performed in an outpatient setting using local anesthetics. Some patients were lost to follow-up; however, the ones who attended regular checkups did not differ significantly from the surgery group and had similar follow-up times.

The overall complications were not significant; however, our data were based on a limited number of studies available. The relative rate of complications in individual studies was lower in the endovascular AVF group. Complications during the first 30 days according to the Society of Interventional Radiology reporting standards²⁹ were reported only in one study by Osofsky et al.¹⁸ We reported the overall complications that occurred in all patients after the procedure and found them to be significantly higher in the surgery group than in the percutaneous group. Some of the major complications reported were rebleeding, thrombosis, and the development of high-flow AVFs leading to congestive symptoms. There have been reports of patients being treated with antiplatelet agents such as clopidogrel, which reduced the risk of thrombosis but did not affect the fistula’s suitability for cannulation.³⁰ In our

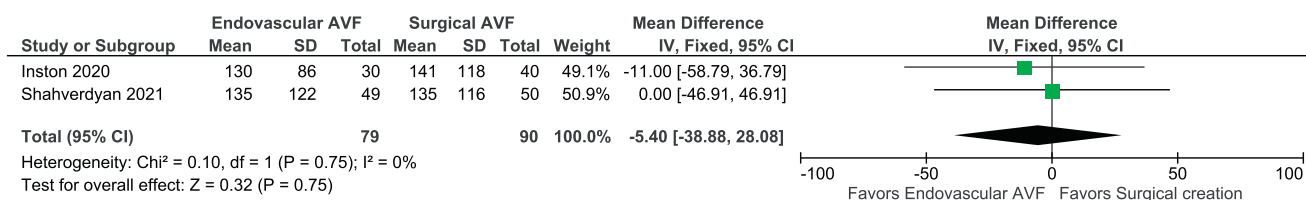


Figure 5. Meta-analysis of time to 2-needle cannulation. Abbreviations: AVF, arteriovenous fistula; IV, interval variable; SD, standard deviation.

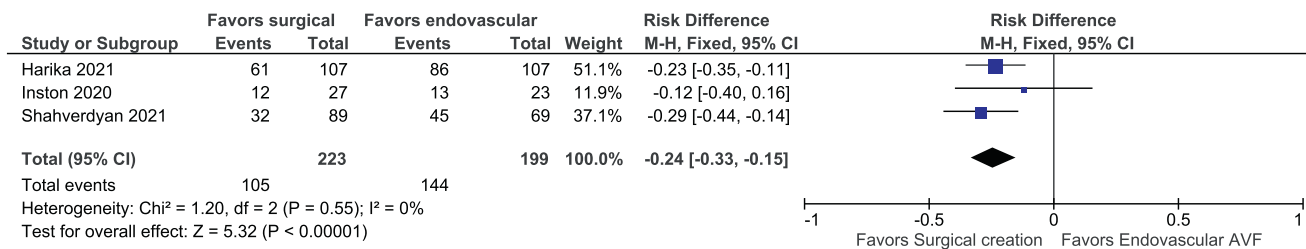


Figure 6. Meta-analysis of primary patency. Abbreviation: AVF, arteriovenous fistula; M-H, Mantel-Haenzsal.

study, we noted that the failure rate was not significantly different between the 2 groups; however, in some reports, the failure rate among surgical fistulas was considerably higher than that among percutaneous ones. These results may vary, as not all hospitals have used these devices, and there is an initial learning curve when using new technology not only for the operators but also for all members of the team involved in the care of the patients receiving dialysis.

When patency rates were compared in the initial follow-up, the results were higher for the surgically constructed fistulas. This may be because the endovascular procedure creates an anastomosis of 4-5 mm in size, which is smaller than surgical anastomosis. These fistulas often require further transluminal angioplasty for maintained patency; however, a study conducted by Beathard et al³¹ showed that the results obtained in a 2-year follow-up in patients with percutaneously created fistulas showed excellent cumulative patency outcomes (92.7%). An important point to address when constructing AVFs is the limited locations available to construct an endovascular fistula. Surgical fistulas can be constructed in numerous locations such as the arm, forearm, and wrist, whereas percutaneous fistulas can only be constructed at the forearm level. This limitation requires further research as not all patients are ideal candidates to have a mid-forearm fistula constructed and may have to undergo a surgical procedure for which they may or may not be ideal candidates. The feasibility of being able to construct endovascular fistulas at various locations may reduce failure rate and improve accessibility. We also noted that the overall number of interventions needed

for fistula maturation was predominant in the percutaneous group. The most common intervention required in the endovascular group was angioplasty, followed by basilic vein embolization and transposition; however, in Novel Endovascular Access Trial,⁹ it was shown that more than half of endovascular AVFs were functional without the need for further intervention. When comparing the number of postprocedural interventions and overall cost, a study conducted by Yang et al³² showed that, in comparison to surgical AVF, the overall costs and number of procedures required for endovascular AVF were lower. All these factors discussed above from previous trials and the results of our study point toward the efficacy of percutaneous AVF creation.

However, certain limitations to overcome and work toward in future studies involve the need for larger randomized clinical trials to be conducted comparing the efficacy of the devices with surgical AVFs. The most important aspect to consider when constructing an AVF endovascularly is patient selection. Not every patient will have a favorable response to the device; hence, we recommend thorough discussions and a multidisciplinary approach in the management of patients with chronic kidney disease. We also recommend the inclusion of patients from different ethnic backgrounds to gauge reproducibility and develop a better understanding. It is our recommendation that dialysis centers should offer training courses for all individuals using these devices to improve their success, and they should aim to improve ease of access in remote areas where high-quality care may not be easily available.

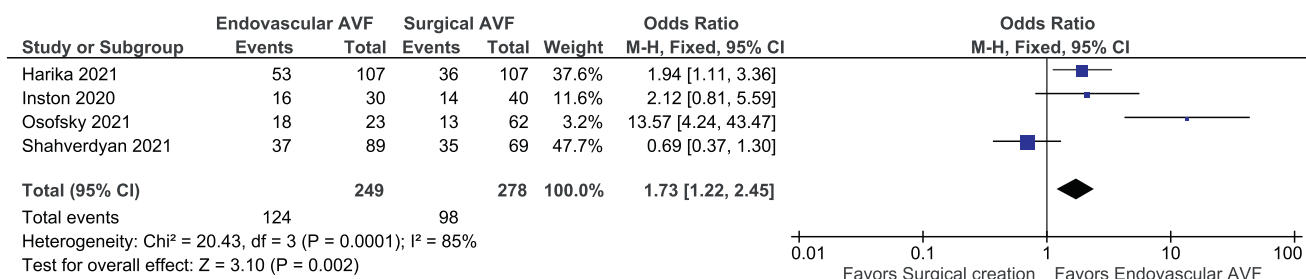


Figure 7. Meta-analysis of further interventions. Abbreviation: AVF, arteriovenous fistula; M-H, Mantel-Haenzsal.

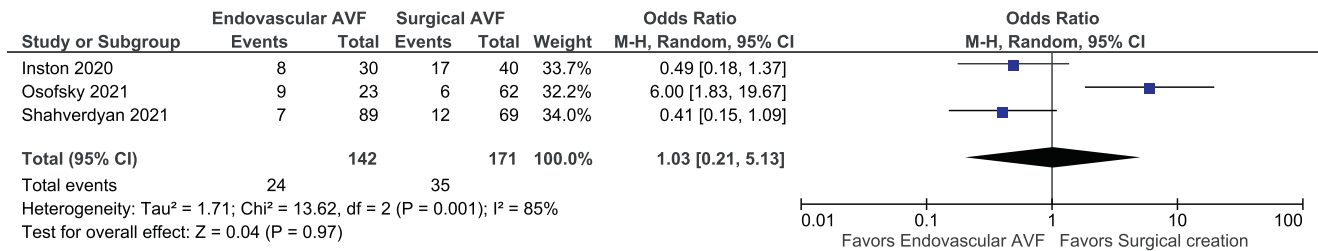


Figure 8. Meta-analysis of failure rate. Abbreviation: AVF, arteriovenous fistula; M-H, Mantel-Haenzsal.

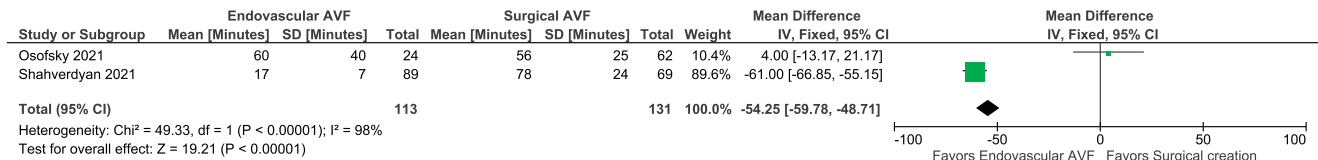


Figure 9. Meta-analysis of procedural time. Abbreviations: AVF, arteriovenous fistula; IV, interval variable; SD, standard deviation.

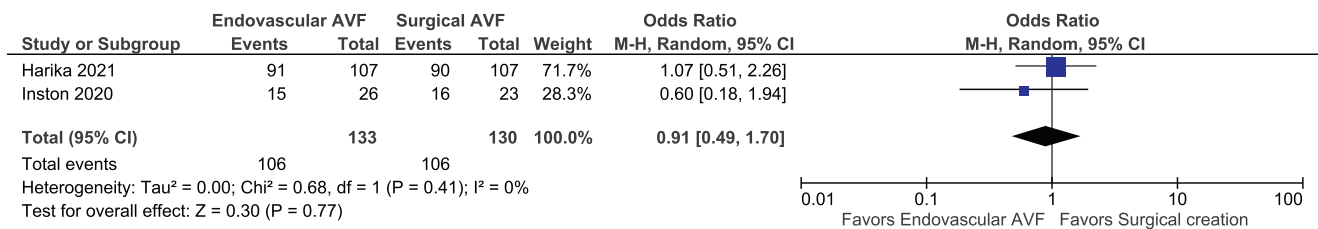


Figure 10. Meta-analysis of secondary patency. Abbreviation: AVF, arteriovenous fistula; M-H, Mantel-Haenzsal.

Endovascularly constructed AVFs offer an excellent alternative as opposed to surgical AVFs. There is a need for further studies to be conducted and an appropriate selection of patients to ensure procedural success in real-world settings. Both procedures have their own benefits and risks, which should be considered by both the providers and patients before proceeding.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF).

Item S1: List of papers searched.

ARTICLE INFORMATION

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accountability for the author's own contributions, and agrees to ensure that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved.

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