## Title

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# Two-Stage Offers No Advantages over Single-Stage Arteriovenous Creation: An Analysis of Multicenter National Data

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## Abstract

**Background:** Traditionally, arteriovenous fistulas (AVF) involving the basilic vein (BV) have been created in 1 or 2 stages to allow time for the vein to enlarge before superficialization for potential better fistula maturation. Previous single institution studies and meta-analyses have found conflicting outcomes between single-stage and 2-stage procedures. Our study aims to use a large national database to assess the difference in outcomes between single-stage and 2-stage procedures for dialysis access.

**Methods:** We studied all patients undergoing BV AVF creation in the Vascular Quality Initiative (VQI) from 2011 to 2021. Patients were split into single-stage or a planned 2-stage procedure for dialysis access. Primary outcomes included dialysis use with index fistula, maturity rate, and number of days from surgery to fistula use. Secondary outcomes included patency (defined by physical exam or imaging on follow-up), 30-day mortality, and postoperative complications (bleeding, steal syndrome, thrombosis, or neuropathy). Logistic regression models were used to assess the association between staged dialysis access procedures and primary outcomes of interest.

**Results:** The cohort consisted of 22,910 individuals of which 7,077 (30.9%) had a 2-staged dialysis access procedure and 15,833 (69.1%) had a single-staged procedure. Average follow-up was 345 days in the single stage and 420 days for 2-stage. Baseline characteristics were significantly different between the 2 groups in terms of medical comorbidities. Primary outcomes were significant for more patients in the 2-stage group undergoing dialysis with the index fistula compared to single stage (31.5% vs. 22.2%, $P < 0.0001$), significant decrease in days to use in

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current dialysis patients (103.9 days single stage versus 141.0 days 2-stage, $P < 0.0001$), and no difference in maturity at follow-up (19.3% single-stage and 17.4% 2-stage, $P = 0.354$). Secondary outcomes revealed no difference in 30-day mortality or patency (89.8% single-stage and 89.1% 2-stage, $P = 0.383$), but a significant difference in postoperative complications with a 2-stage procedure compared to 1-stage (1.6% vs. 1.1%, $P = 0.026$). Finally, a spline model was used to determine that a preoperative vein of 3 mm or less could be a cutoff in which a 2-stage procedure might be beneficial.

**Conclusions:** This study demonstrates that when dialysis access fistulas are created using the BV, there is no difference in maturity rate or 1-year patency when assessing single-stage versus 2-stage procedures. However, 2-stage procedures significantly delay the time of first use of the fistula and increase postoperative complications. Therefore, we suggest performing single stage procedures when the vein is of appropriate diameter to minimize multiple procedures, complications and expedite time to maturity.

## INTRODUCTION

In patients being planned for hemodialysis, an autogenous arteriovenous fistula (AVF) is the preferred route for vascular access due to lower rates of morbidity, mortality, and costs compared with grafts or catheters.[1–3] Though radiocephalic and brachiocephalic fistulas are the first and second choices for AVF procedures, when the cephalic vein is unavailable due to size, scarring or other issues, the brachiobasilic fistula becomes the procedure of choice.[4]

The basilic vein to brachial artery fistula (BBF) is developed by creating a fistula between the end of the transposed basilic vein and anterior aspect of the brachial artery and has been used for decades with good outcomes.[5] Originally developed as a single-stage (primary) procedure, staging of BVF (2-stage procedure) was subsequently introduced, with the first stage of the procedure involving a brachiobasilic arteriovenous fistula. Once the basilic vein is appropriately matured, then the second stage occurs via superficialization, either by transposition or elevation.[6]

A single-center retrospective nonrandomized study with 94 participants undergoing a single-stage basilic vein transposition found it to be a feasible surgical option with reasonable patency and complication rates.[7] In another single-center retrospective study involving 96 patients, 2-stage basilic vein transposition was superior to 1-stage basilic vein transposition with respect to postoperative complications and fistula maturation.[8] In a meta-analysis comparing 1-stage and 2-stage BBFs, there were no differences in failure and patency rates, aside that the 2-stage procedure was used mostly in smaller basilic veins.[9] A systematic review and meta-analysis of randomized trials comparing 2-stage with 1-stage BVF in 3 randomized controlled trials of 126 patients found evidence to suggest that 2-stage BBFs achieved higher maturation rates when compared to 1-stage BBFs.[10]

With these mostly conflicting outcomes in tests of superiority, a large prospective clinical trial might be required to adequately settle the debate of which technique is superior. In the meantime, analysis of a large national database would provide useful real-world outcomes of both procedures and may answer questions on which technique is more useful and under which circumstances. A previous study using multi-institution data was conducted on 2,600 patients and found no difference in patency between single and 2-stage procedures.[11] In this study utilizing the Vascular Quality Initiative (VQI) from 2011 to 2021, we studied all patients undergoing BBF creation with an objective to assess the difference in outcomes between single-stage and 2-stage procedures for dialysis access in a larger sample than the previous study and with models to predict preoperative vein cutoffs.

# METHODS

## Dataset

This study was conducted using the VQI hemodialysis access dataset after obtaining approval from the VQI Research Advisory Committee (Protocol #4748). VQI is a multi-institutional deidentified prospectively collected database including around 200 preoperative, intraoperative, and postoperative variables for up to 1 year at over 800 centers in the United States and Canada.[12] Individual consent and Institutional Review Board approval are waived given the deidentified nature of the database.

## Population

A retrospective analysis was performed on all patients who had an AVF between 2011 and 2021. Patients with missing data regarding 2-stage procedures were excluded, as well as patients with an unplanned procedure. The cohort was split into 2 groups, 1 with planned 2-stage brachiobasilic fistulas (BBFs) and 1 with single-stage BBF.

## Variables

Baseline characteristics included demographics [age, sex, race, body mass index], comorbidities [diabetes, hypertension, congestive heart failure (CHF), coronary artery disease (CAD) and chronic obstructive pulmonary disease (COPD), peripheral arterial disease], smoking history, and preoperative medications [aspirin, P2Y12 inhibitors, and statins]. Additionally, we collected data on previous history of dialysis access and preoperative artery and vein size.

## Outcomes

Primary outcomes included dialysis use with the index fistula (functional patency), rate of maturity, and number of days from surgery to fistula use. Secondary outcomes focused on primary patency defined by physical exam or imaging on follow-up as access patency not requiring any intervention to improve blood flow, 30-day mortality, and postoperative complications including bleeding, steal syndrome, thrombosis, and neuropathy.[13]

## Statistical Analysis

Continuous and binary variables were analyzed using Student's *t*-test and Pearson's chi-squared test respectively. Univariate and multivariate logistic regression models were used to analyze outcomes of interest. There were a total of 141 centers in the study and all final models were clustered by center ID to account for intragroup correlation. Hosmer-Lemeshow goodness of fit test and area under the receiver operator curve were used to assess model fit and accuracy, respectively. Kaplan–Meier analysis and log rank test were used to evaluate patency over 1 year. Finally, a spline model was performed to determine preoperative vein diameter significance for patency and included in the logistic regression model. Final models included statistically and clinically relevant variables which were chosen based on a stepwise backward selection with $P < 0.1$. A $P$-value <0.05 was considered statistically significant. All analyses were performed using Stata 16.1 (StataCorp, College Station, Texas).

## RESULTS

The final cohort consisted of 22,910 individuals; 15,833 (69.1%) had single-stage and 7,077 (30.9%) had 2-stage BBF. On assessment of demographic and clinical baseline characteristics, the 2-stage group was significantly younger, had more females, more individuals who identified as the White race, more individuals with type-II diabetes, less individuals with CAD or percutaneous coronary intervention, and greater proportion of individuals with COPD (Table I). There was no difference in preoperative aspirin, P2Y12 inhibitors, or statin use. Additionally, the 2-stage group had significantly larger preoperative vein diameter, 3.8 cm compared to 3.5 cm in the single stage group ($P < 0.0001$) and preoperative artery diameter 4.4 cm compared to 4.1 cm ($P < 0.0001$).

### Primary and Secondary Outcomes

On univariate analysis, there was a significantly greater proportion of individuals using their index fistula for dialysis in the 2-stage group, 31.5% compared to 22.2% in the single-stage group ($P < 0.0001$). Additionally, there was a significantly longer period of time from surgery date to fistula use for patients already on dialysis in the 2-stage group, 141.0 days compared to 103.9 days in the single stage group ($P < 0.0001$). However, there was no significant difference in percentage of mature fistulas in each group, 17.4% vs. 19.3% ($P = 0.354$) in 2-stage versus single-stage, respectively or in patency (defined by physical exam or imaging by 1 year) 89.1% in the 2-stage group and 89.8% in the single-stage group ($P = 0.383$) (Table II).

Table III compared secondary postprocedure outcomes between the 2 groups and found a significantly higher percentage of postoperative complications (1.6% vs. 1.1%, $P = 0.026$), including bleeding (1.2% vs. 0.8%, $P = 0.042$) and steal syndrome (0.21% vs. 0.07%, $P = 0.052$) in the 2-stage group compared to the single stage. The majority of the postoperative bleeding complications did not require treatment and were not clinically significant in both single-stage and 2-stage groups. Additionally, there were no differences in 30-day mortality, postoperative thrombosis, or postoperative neuropathy.

On unadjusted analysis, there was a 60% increased odds of dialysis use with the index fistula in the 2-stage group compared to the single-stage group (odds ratio (OR) 1.6, 95% confidence interval (CI) = 1.5–1.8, $P < 0.0001$). However, after adjusting for age, gender, race, body mass index, diabetes, CAD, history of CABG, COPD, previous dialysis access before surgery and anesthesia type, there was no significant difference in the odds of mortality, patency, dialysis access with the index fistula and maturity between the 2-stage and single-stage groups (Table IV).

### Outcomes Including Vein Diameter

Figures 1 and 2 represent spline models for both single-stage and 2-stage BBFs. Both images demonstrate the relationship between preoperative vein diameter and patency. The goal of these models is to elucidate the point along a continuous spectrum where the vein size becomes significant. Figure 1 describes the single stage cohort and Figure 2 describes the 2-stage cohort. Both figures show that at the significant point of a 3 mm preoperative vein size and greater, both single-stage and 2-stage procedures can be performed without sacrificing patency.

Given the results of the spline model, further logistic regression models were run with previously stated clinical and demographic variables in addition to preoperative vein size. Vein size was tested at multiple cutoffs: 2 mm, 3 mm, and 4 mm. Table V indicates that after adjustment for both a 2 mm vein cutoff and 3 mm vein cutoff, there was no significant difference in odds of mortality, dialysis access with the index fistula or maturity between the 2-stage and single-stage groups. In terms of patency, both the spline model and Table V show that for a vein less than 2 mm compared to a vein greater than 2 mm, there is a 2.4-fold increased patency in the 2-stage group compared to that in the single-stage group. Similarly, in a vein less than 3 mm compared to one greater than 3 mm, there is a 3.0-fold increased patency in the 2-stage group compared to the one-stage.

### Long-Term Outcomes

Figure 3 represents a Kaplan–Meier analysis to assess patency for both single-stage and 2-stage procedures. After 1 year of follow-up we had significant attrition in our cohort, and therefore results were reported up to 1 year. We had follow-up data on 59% of the single-stage cohort and 73% of the 2-stage cohort. At 1-year, patency in the single-stage group was 47% and 53% in the 2-stage group ($P = 0.029$).

## DISCUSSION

In this study to assess the difference in outcomes between single-stage and 2-stage procedures for dialysis access, we found no significant difference in the odds of 30-day mortality, primary patency, dialysis access with the index fistula (functional patency), or maturity between the 2-stage and single-stage groups. Similar to our findings, a single-center study looking at only single-stage procedures found that patency rates at 1 year were 84% but found a much higher proportion of postoperative complications (40%) which could be due to a significantly smaller sample size of only 94 patients.[7] Additionally, a meta-analysis found that there was no difference in failure or patency rates between single-stage and 2-stage procedures.[9] However, a different meta-analysis found that 2-stage procedures had higher maturity rates, but this included only randomized control trials which could explain why we did not see the same result.[10] A retrospective review of 77 patients found that the presence of catheter dialysis was higher in the 2-stage group (43% vs. 14% in single stage); however, ultimately both groups had similar initial failure rates and secondary interventions.[14] With the unsettled debate surrounding choosing between single-stage or 2-stage techniques in BBFs, surgeons could benefit from knowing which procedure offers the most advantage.

The single-stage procedure offers the advantage of a shorter waiting time before fistula cannulation, which is consistent with our finding of a 30-day longer wait on average for fistula use in the 2-stage group compared to the single-stage group. The single-stage procedure is also considered to be more cost-effective as resources are mobilized at a single time point for the procedure.[15] Single stage fistulas have been shown to have longer procedure times, increased surgical skill, and longer incisions with a theoretical risk of a less stable fistula.[16] Therefore, the 2-stage procedure offers the promise of a more robust basilic vein with fewer expected complications and higher patency rates.[17] With this potential advantage not seen in our analysis, as we showed no difference in primary and functional patency, and with the increase in postoperative complications, we would be cautious in recommending the 2-stage procedure over the single-stage procedure based on patency rates alone. A single-center study divided patients in 2 groups based on basilic vein diameter, basilic vein less than 3 mm underwent a 2-stage procedure and basilic vein greater than 3 mm underwent single-stage BBF, which is similar to what our spline model predicted. This study found that 2-stage BVT had lower postoperative complications and higher fistula maturation, which was different from our study and could be due to a much smaller sample size.[8]

Contrary to our findings, Reynolds et al. retrospectively reviewed 90 patients from 2 different institutions and found that 2-stage procedures have better functional patency, as well as better primary and secondary patency at 1 year and 2 years.[18] This was echoed by multiple single-center retrospective reviews which found 2-stage BBFs were found to have improved patency rates at 1 year compared to single-stage BBFs.[19–22] However, all 3 studies were conducted at single institutions with small variation in surgeons. Further single-center studies have found that single-stage procedures could offer modest maturation increases, 90% compared to 75% in 2-stage BBFs.[23]

Similar to our study, a single institution study in the United Kingdom found no difference in patency between the 2 groups at 5 years.[24] In a previous small scale VQI study, Tan et al. looked at approximately 1,200 single-stage and 1,400 2-stage BBFs and found that similar to our study, patients who have smaller basilic veins are better severed with a 2-stage procedure.[11] Our study differed from Tan et al. due in part to the spline model that was used to determine the preoperative vein diameter cutoff that would be best for a single-stage versus 2-stage procedure.[11] Additionally, similar to our study the smaller VQI study found there was no difference in patency between single-stage and 2-stage BBFs. Our study contributes to the literature because it is the largest review of single-stage versus 2-stage procedures, confirms the previous VQI study finding of similar patency between the 2 groups, and includes preoperative vein diameters in the final regression model based off spline models.[11] Additionally, a systematic review of 12 studies found no differences in primary patency rates between the 2 groups at 1 year.[25] This is further supported by a meta-analysis of 37 manuscripts that found equivalent 1-year patency and complication rates between single-stage and 2-stage BBFs.[26]

Finally, our study found that the only potential benefit of a 2-stage BBF was in veins less than 3 mm in diameter. There was no difference in patency between single-stage and 2-stage BBFs based on a preoperative vein size of 4 mm or larger. This is important because previous studies have studied the utility of a BBF based on a basilic vein size of 3–4 mm or greater.[1,27,28]

### Limitations

Our study has several limitations. The retrospective nature of our study is inherent with biases and disadvantages that randomization could have eliminated. For example, in centers with large numbers of patients requiring dialysis urgently, surgeons might favor the single-stage procedure over the more time-consuming 2-stage procedure, possibly accounting for a higher number of patients selected by surgeons in our study for the 1-stage procedure compared to the 2-stage procedure. Additionally, the VQI database has poor long-term follow-up and therefore long-term patency rates are difficult to ascertain and currently the VISION database linked to Medicare does not contain dialysis access data. Additional limitations include lack of data regarding fistula abandonment, secondary patency rates, cause of end-stage renal disease and lack of standardized criteria for selecting single-stage versus 2-stage procedures.

## CONCLUSION

In this large multicenter population study, we were able to compare real world outcomes of single-stage versus 2-stage BBF. We found that for veins 3 mm or larger, a 2-stage BBF does not offer an advantage over a single-stage BBF in terms of mortality, patency, dialysis use with the index fistula, or maturity. There was also an increased risk of postoperative complications and an average of 30-day delay in access use for 2-stage BBF. Therefore, we suggest 2-stage BBF should be performed only in patients with a small basilic vein less than 3 mm. Single-stage BBF should be considered in all patients with a vein at least 3 mm in diameter to decrease the time to use, the need for catheter, prevent multiple operations and reduce the staggering cost of hemodialysis.

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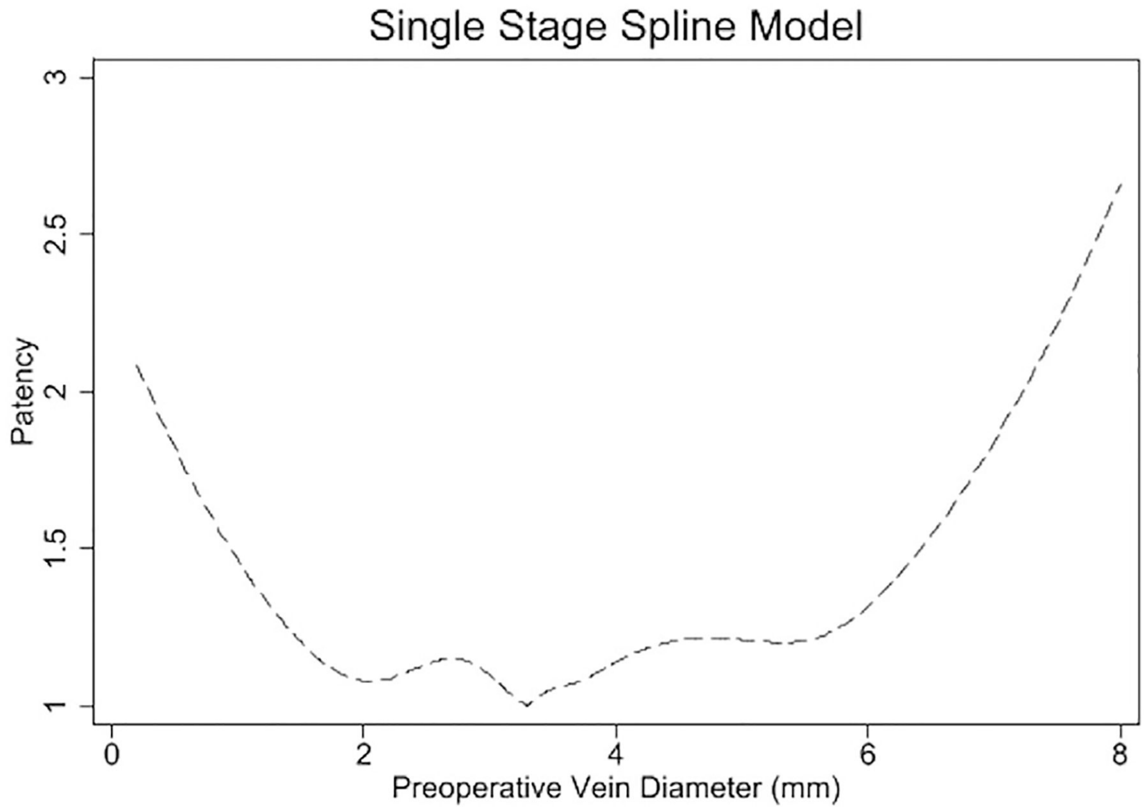


**Fig. 1.**
Spline model for single stage AV fistula.

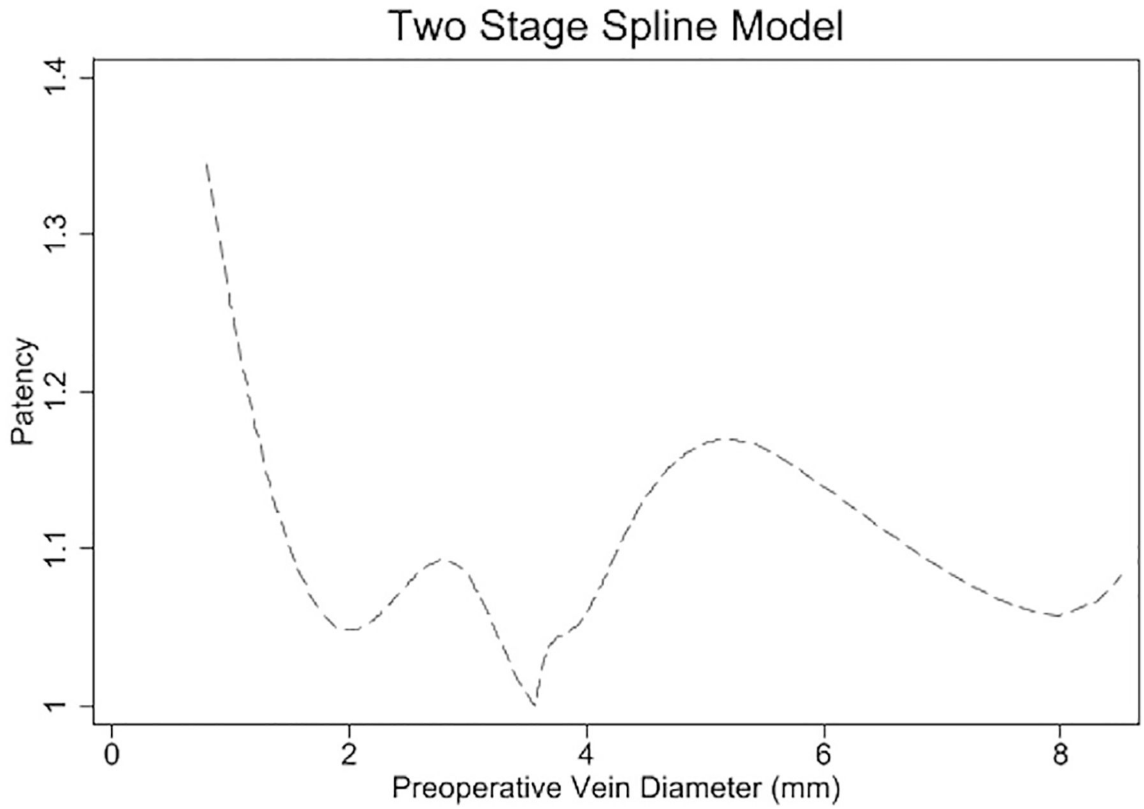


**Fig. 2.**
Spline model for two stage AV fistula.

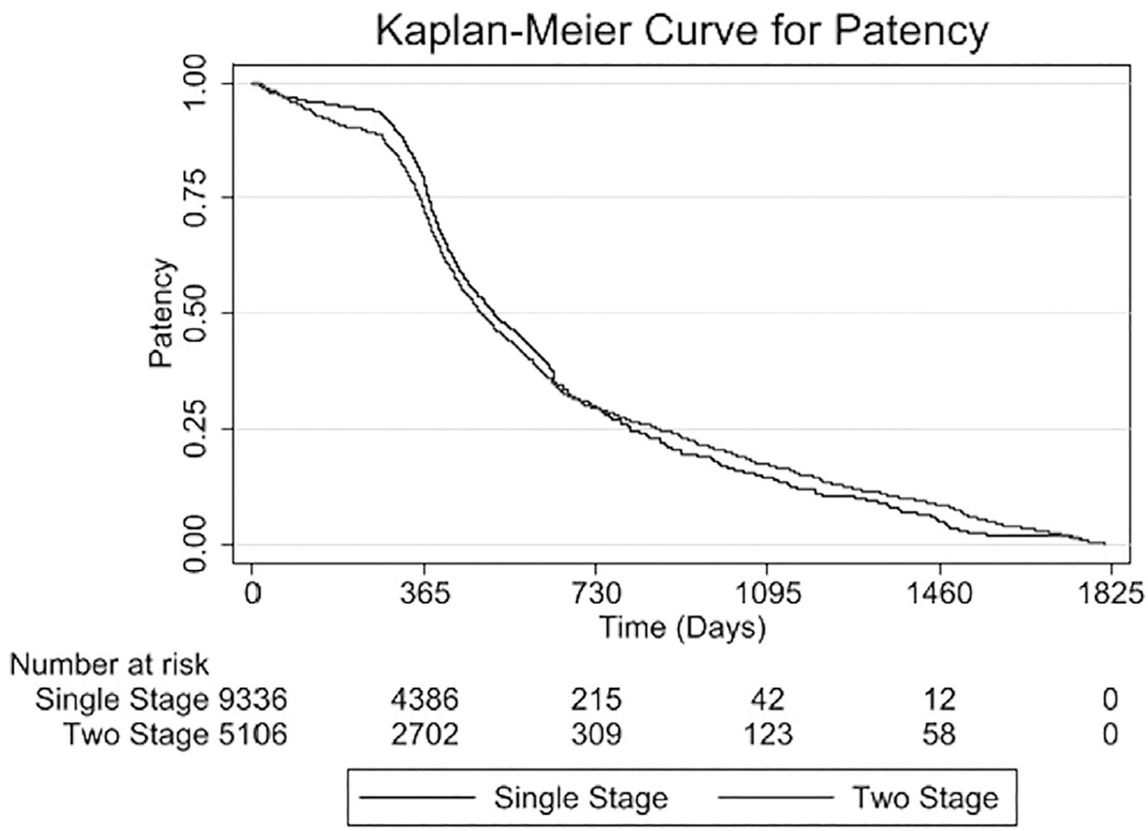


**Fig. 3.**

Kaplan–Meier model for patency over 5 Years.

## Table I.

Baseline characteristics

| Mean ± SD *N* (%) | Single stage 15,833 (69.1) | Two-stage 7,077 (30.9) | *P* value |
|---|---|---|---|
| Age (years) | 61.8 ± 14.6 | 61.2 ± 14.7 | 0.0067 |
| Male | 9,369 (59.2) | 3,506 (49.60) | <0.0001 |
| Race: White | 8,733 (55.2) | 3,038 (43.0) | <0.0001 |
| Body Mass Index kg/m$^2$ | 29.84 ± 7.85 | 29.10 ± 8.89 | <0.0001 |
| Smoker | 8,132 (51.5) | 3,573 (50.6) | 0.217 |
| Hypertension | 14,869 (94.5) | 6,635 (94.6) | 0.598 |
| Type 2 Diabetes | 5,364 (47.6) | 3,237 (52.8) | <0.0001 |
| Coronary Artery Disease | 3,078 (21.3) | 1,352 (19.9) | 0.025 |
| Coronary artery bypass graft or percutaneous coronary intervention | 3,045 (19.5) | 1,275 (18.1) | 0.014 |
| Congestive Heart Failure | 5,073 (32.1) | 2,247 (31.8) | 0.645 |
| Chronic Obstructive Pulmonary Disease | 2,800 (17.7) | 1,364 (19.3) | 0.004 |
| Peripheral Arterial Disease | 487 (6.4) | 341 (6.5) | 0.873 |
| Preop Aspirin Use | 4,707 (43.6) | 984 (41.9) | 0.120 |
| Preop P2Y12 Inhibitor Use | 1,184 (11.0) | 271 (11.5) | 0.430 |
| Previous Dialysis Access | | | 0.338 |
| Previous Percutaneous Catheter | 448 (6.4) | 94 (5.6) | |
| Previous Tunneled Catheter | 6,316 (90.4) | 1,544 (91.6) | |
| Previous Arteriovenous Access | 221 (3.2) | 48 (2.9) | |
| Preop Statin Use | 6,590 (61.1) | 1,467 (62.4) | 0.230 |
| Previous dialysis access | 2,107 (19.5) | 677 (28.9) | <0.0001 |
| Preoperative Artery Diameter (cm) | 4.05 ± 1.36 | 4.43 ± 1.29 | <0.0001 |
| Preoperative Vein Diameter (cm) | 3.5 ± 1.6 | 3.8 ± 1.8 | <0.0001 |
| Anesthesia Type | | | <0.0001 |
| Local | 3,480 (22.2) | 2,293 (32.5) | |
| Regional | 5,733 (36.3) | 1,942 (27.5) | |
| General | 6,591 (41.7) | 2,818 (40.0) | |

## Table II.

Univariate analysis of primary outcomes

| Mean ± SD *N* (%) | Single stage 15,833 (69.1) | Two-stage 7,077 (30.9) | *P* value |
|---|---|---|---|
| Dialysis use with index fistula | 1,455 (22.2) | 1,210 (31.5) | <0.0001 |
| Maturity | 243 (19.3) | 99 (17.4) | 0.354 |
| Days from surgery to fistula use[a] | 103.9 ± 91.2 | 141.0 ± 93.8 | <0.0001 |
| Patency | 3,230 (89.8) | 2,594 (89.1) | 0.383 |

[a]Patients who were on dialysis before the current procedure.

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## Table III.

Univariate analysis of secondary outcomes

| **Mean ± SD *N* (%)** | **Single stage 15,833 (69.1)** | **Two-stage 7,077 (30.9)** | ***P* value** |
|---|---|---|---|
| Length of Stay (days) | 1.05 ± 6.22 | 0.89 ± 8.71 | 0.153 |
| Mortality | 41 (0.26) | 17 (0.24) | 0.794 |
| Postoperative Complications | 116 (1.1) | 38 (1.6) | 0.026 |
| Postoperative Bleeding | 83 (0.8) | 28 (1.2) | 0.042 |
| Postoperative Steal Syndrome | 8 (0.07) | 5 (0.21) | 0.052 |
| Postoperative Thrombosis | 22 (0.2) | 5 (0.21) | 0.928 |
| Postoperative Neuropathy | 3 (0.03) | 0 (0) | 0.419 |
| Flow Volume (mL) | 1,088.63 ± 737.39 | 1,214.78 ± 816.01 | <0.0001 |
| Length of follow-up (days) | 344.74 ± 201.97 | 420.35 ± 319.24 | <0.0001 |
| Time from surgery until access first use (days) | 116.35 ± 100.95 | 145.52 ± 98.35 | <0.0001 |

## Table IV.

Unadjusted and adjusted multivariate analysis for primary and secondary outcomes

| Variable | Unadjusted odds ratio | 95% confidence interval | *P* value | Adjusted odds ratio[a] | 95% confidence interval | *P* value |
|---|---|---|---|---|---|---|
| Mortality | 0.93 | 0.53–1.63 | 0.794 | 1.13 | 0.18–7.14 | 0.900 |
| Patency | 0.93 | 0.80–1.09 | 0.383 | 2.11 | 0.72–6.27 | 0.178 |
| Dialysis with Index Access | 1.62 | 1.48–1.77 | <0.0001 | 1.45 | 0.40–5.31 | 0.574 |
| Maturity | 0.89 | 0.68–1.15 | 0.354 | 1.08 | 0.57–2.03 | 0.823 |

Reference: Single stage.

[a] Adjusted for age, gender, race, body mass index, diabetes, coronary artery disease, history of coronary artery bypass graft, chronic obstructive pulmonary disease, dialysis access type prior to surgery, anesthesia type.

## Table V.

Adjusted odds ratios including preoperative vein size

| Variable | Adjusted odds ratio[a] with 2 mm vein cutoff | 95% confidence interval | *P* value | Adjusted odds ratio[a] with 3 mm vein cutoff | 95% confidence interval | *P* value | Adjusted odds ratio[a] with 4 mm vein cutoff | 95% confidence interval | *P* value |
|---|---|---|---|---|---|---|---|---|---|
| Mortality | 1.08 | 0.17–6.84 | 0.934 | 1.05 | 0.16–6.87 | 0.963 | 1.02 | 0.16–6.47 | 0.981 |
| Patency | 2.35 | 1.05–5.30 | 0.038 | 2.96 | 1.02–8.63 | 0.046 | 2.12 | 0.73–6.17 | 0.170 |
| Dialysis with Index Access | 1.45 | 0.41–5.22 | 0.569 | 1.44 | 0.39–5.29 | 0.581 | 1.49 | 0.40–5.62 | 0.553 |
| Maturity | 1.02 | 0.54–1.93 | 0.947 | 1.02 | 0.54–1.94 | 0.948 | 1.06 | 0.56–1.99 | 0.866 |

Reference: Single stage.

[a] Adjusted for age, gender, race, body mass index, diabetes, coronary artery disease, history of coronary artery bypass graft, chronic obstructive pulmonary disease, dialysis access type before surgery, anesthesia type.