Review Article

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Patency of ePTFE Arteriovenous Graft Placements in Hemodialysis Patients: Systematic Literature Review and Meta-Analysis

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Abstract

Arteriovenous grafts (AVGs) are an appropriate option for vascular access in certain hemodialysis patients. Expanded polytetrafluoroethylene (ePTFE) has become the dominant material for such grafts, due in part to innovations in graft design and surgical interventions to reduce complications and improve patency rates. Comprehensive evidence syntheses have not been conducted to update AVG performance in an era in which both access choice and ePTFE graft functioning may have changed. We conducted a systematic review and meta-analysis summarizing outcomes from recent studies of ePTFE AVGs in hemodialysis, following PRISMA standards. Literature searches were conducted in multiple databases to identify observational and interventional studies of AVG patency and infection risk. Primary, primary-assisted, and secondary patency rates were analyzed at 6, 12, 18, and 24 months postplacement. Kaplan–Meier graft survival plots were digitized to recreate individual patient-level data. Patency rates were pooled using a random effects model. We identified 32 studies meeting our selection criteria that were published from 2004 through 2019. A total of 38 study arms of ePTFE grafts were included, representing 3381 AVG accesses placed. The mean primary, primary-assisted, and secondary patency rates at 1 year were 41% (95% CI, 35% to 47%), 46% (95% CI, 41% to 51%), and 70% (95% CI, 64% to 75%), respectively. Mean 24-month patency rates were 28% (95% CI, 22% to 33%), 34% (95% CI, 27% to 41%), and 54% (95% CI, 47% to 61%), respectively. A high degree of heterogeneity across studies was observed. Overall risk of infection was not consistently reported, but among available studies the pooled estimate was 9% per patient-year (95% CI, 6% to 12%). This meta-analysis provides an up-to-date estimate of the performance of ePTFE AVGs, within the context of improved graft designs and improved interventional techniques.

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Introduction

Current National Kidney Foundation guidelines recommend an arteriovenous fistula (AVF) as the first access for hemodialysis (1). However, primary failure rates for AVF remain high (over 20%) and for many patients AVF is not a viable option due to vascular anatomy or to other factors (2,3). In these cases, an arteriovenous graft (AVG) is recommended for vascular access in the upper extremity. One of the most widely used graft materials is expanded polytetrafluoroethylene (ePTFE).

The use of AVGs has historically been hampered by low patency rates, with reported secondary patency of 76% at 6 months and 55% at 18 months (4). In addition, ePTFE grafts can suffer from high rates of complications, including infections, thrombosis, and steal syndrome (4). Recent advances in prosthetic graft material engineering may have contributed to an increase in the durability of ePTFE (5,6), such as advances in coating technology such as covalent heparin modifications (7). However, there has been no recent comprehensive evaluation of ePTFE AVG functional patency rates when used for hemodialysis access. Furthermore the "fistula first" initiative has changed patient selection criteria for placement of an AVG rather than an AVF. Therefore, we considered it important for present-day hemodialysis access practice to conduct a systematic review and meta-analysis in order to summarize key outcomes in recent studies of ePTFE vascular access grafts.

Materials and Methods

Study Design

This systematic review and meta-analysis was conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance (8). Methods of the analysis, inclusion, and exclusion criteria were specified in advance and documented in a protocol, with search terms identified *a priori*.

The study population consisted of patients with CKD or ESKD who were either preparing for, or currently on, chronic hemodialysis treatment using a ePTFE graft. Inclusion criteria for studies to be considered in this meta-analysis were: (*1*) at least one

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study arm included a ePTFE graft; (2) study described newly created AVGs (incident grafts), as opposed to only graft revisions; and (3) studies published in English. Clinical trials, observational study designs, and systematic reviews were included. Studies were excluded if: (1) study arms had fewer than 30 patients receiving ePTFE grafts; (2) patients were treated before the year 2000; (3) no patency results were reported at 6, 12, 18, or 24 months; (4) the study was exclusively pediatric; and (5) the study only included lower-extremity dialysis access grafts, which are known to have substantially different patency and infection outcomes than upper-extremity grafts. Studies using only Hemodialysis Reliable Outflow grafts with no ePTFE study arm were excluded.

Literature Search

Literature searches were conducted in November 2019 in the Medline, Embase, Cochrane Library, and Clinicaltrials.gov databases. A flow diagram of the study selection and inclusion process is shown in Figure 1. The search terms used in each database are found in Supplemental Table 1. Additional studies were identified through searching the reference lists of included systematic reviews.

Studies were screened for eligibility by two reviewers at the levels of abstract and full text. Disagreements were resolved by consensus. Data items were extracted into a spreadsheet developed in advance of the review. Data elements extracted included: study characteristics [objective, study type, inclusion/exclusion criteria, country, type of intervention(s), end points, funding, and number of sites]; patient characteristics (including demographics and comorbid conditions); graft characteristics (including type/brand, size, and location); patency end points; and complications (including infections, interventions, and steal).

Risk of bias in individual studies was evaluated using the approach described by Higgins *et al.* (9). Because most of the included studies were observational, we adapted a tool described by Al-Jaishi that was used in a systematic review of AVF (2).

End Points and Definitions

The patency analysis was categorized using the definitions provided by Sidawy (10). Primary unassisted patency was defined as "the interval from access placement until any intervention designed to maintain or re-establish patency, access thrombosis, or the time of measurement of patency." Primary-assisted patency was "the interval from access placement until access thrombosis, or the time of measurement of patency, including intervening manipulations (surgical or endovascular interventions) designed to maintain

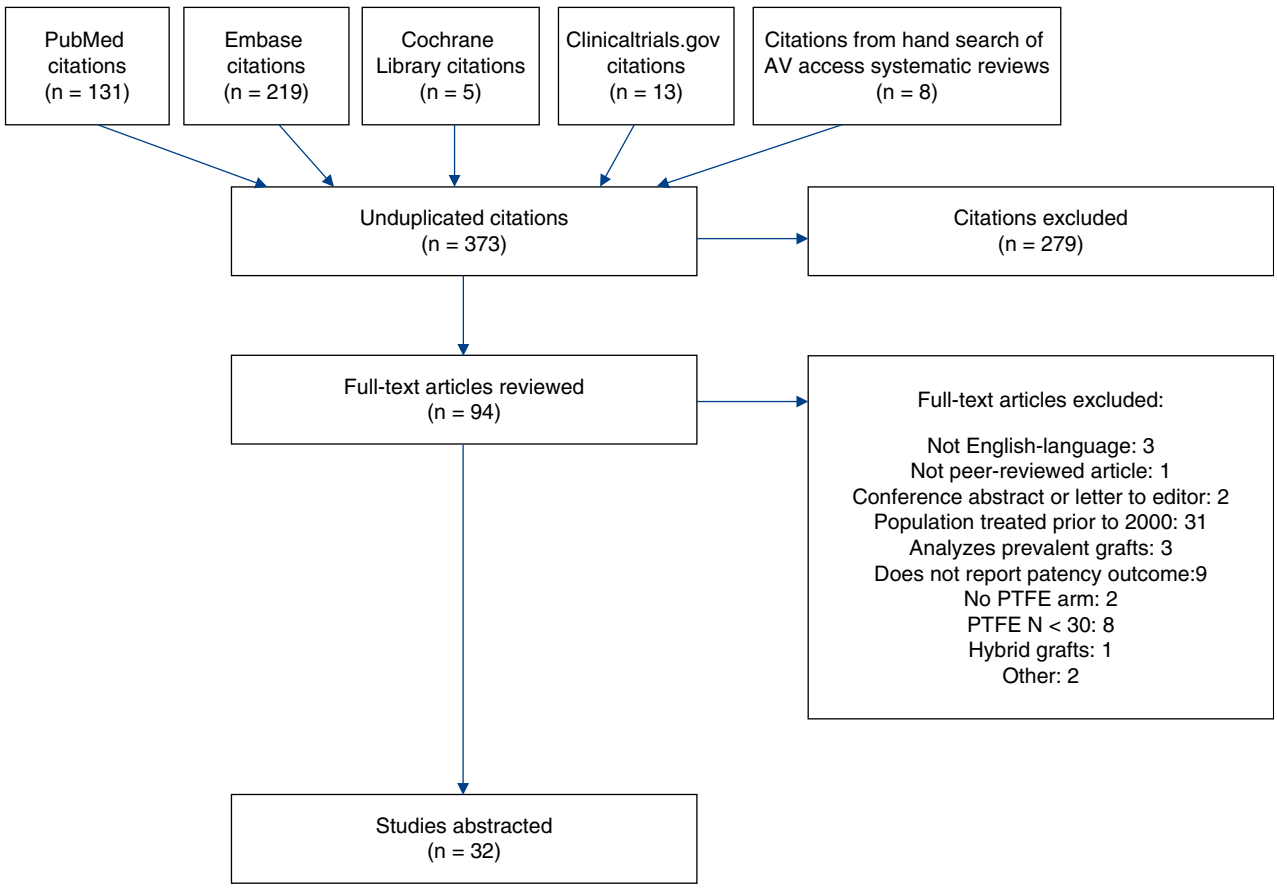

Figure 1. | **Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram.** ePTFE, expanded polytetrafluoroethylene.

the functionality of a patent access." Secondary patency was "the interval from access placement until access abandonment, thrombosis, or the time of patency measurement including intervening manipulations (surgical or endovascular interventions) designed to re-establish functionality in a thrombosed access."

The occurrence of infections and complications reported in patients receiving an AVG was also abstracted. In studies that did report infection rates, there was commonly an overall percentage of patients with infections over the course of the entire study period. Infection rates per patient-year were estimated from the mean follow-up period for each study.

Statistical Analyses

Meta-analyses of proportions were conducted using random effects models employing Stata (StataCorp LP, V.16.0) (11,12). Primary outcomes were graft patency measures: primary, primary-assisted, and secondary patency, measured at 6, 12, 18, and 24 months. Stratified analyses were also performed on variables selected *a priori* to potentially affect the outcomes of interest, such as sex, race, diabetes, country setting (US versus ex-US), study design (observational prospective, observational retrospective, or interventional), risk of bias, and industry funding. Heterogeneity was measured using the I^2 statistic, which is a measure of the proportion of total variation in mean estimates that is due to heterogeneity across individual studies (13).

For patency outcomes, most included studies used time-to-event analysis and published survival curves using the Kaplan–Meier method (14). If patency outcomes were reported in text and also published in survival curves, the originally reported in-text data were used, provided that a measure of variance was included. For studies that did not report patency outcomes in text or tables, a published algorithm (15) was used to reproduce individual patient data using DigitizeIt software. Each line in a Kaplan–Meier curve and the resulting output was used, in coordination with the study's stated patency results, to estimate survival summary statistics for each study. Patencies at 6, 12, 18, and 24 months, along with their SEMs, were computed, which were then entered into the meta-analyses. No extrapolation of patency outcomes was performed; patency estimates were digitized only at reported time points from Kaplan–Meier curves. As a quality control measure for the digitization software, a sample of papers that reported patency in-text and also had Kaplan–Meier curves was used to compare accuracy of digitization output. Where patency data were not reported in the text or tables, digitized Kaplan–Meier data from the published report were substituted. Some curves could not be digitized because of the poor quality of the original publication graphics. Potential publication bias among included studies was assessed using the methods described by Egger, including the use of funnel plots that indicate the direction of potential missing outcomes on the basis of effect sizes of available outcomes (16).

Ethics Approval

As all data were obtained from published scientific articles, this study was exempt from Institutional Review Board review in accordance with 45 Code of Federal Regulations (CFR) 46.101(b) (4).

Results

Included Publications

A total of 32 studies were included in the analysis (Figure 1) (17–48). Publication dates ranged from 2007 through 2019, representing relatively contemporary clinical experience with dialysis access. Characteristics of included studies (Supplemental Tables 2–4) indicate that a total of 38 study arms of ePTFE grafts were included, representing 3381 AVG accesses placed. Fourteen countries were represented, with 13 studies solely from the US. Twenty-one studies (65.6%) were retrospective reports, 6 (18.8%) were prospective observational studies, and 5 (15.6%) were randomized clinical trials. Risk of bias in reported study design issues was assessed to be low for 20 (62.5%) of the studies.

Primary and Primary-Assisted Patency

Overall patency results for the 32 studies included in this meta-analysis are shown in Table 1 (for each patency outcome, rates reported in the manuscript were within 1% of the data digitized from the published Kaplan–Meier curves, apart from a single primary assisted patency rate for which the difference was 5%, where the stated value was used). Patency rates followed expected patterns over time. Primary patency at 6 months (56%; 95% confidence interval [95% CI], 51% to 62%) was higher than at 24 months (28%; 95% CI, 22% to 33%); primary-assisted patency rates were a few percentage points higher than primary rates (59%; 95% CI, 52% to 67%) at 6 months, with some increase in the gap over primary patency with time (34%; 95% CI, 29% to 39%) at 24 months. The 95% CIs for primary and primary-assisted patency overlapped for all time periods reported.

Secondary Patency

For ePTFE grafts, the average secondary patency in these 32 studies trended from 80% (95% CI, 75% to 84%) at 6 months to 70% (95% CI, 64% to 75%) at 12 months, to 59% (95% CI, 53% to 65%) at 18 months and 54% (95% CI, 47% to 61%) at 24 months.

Statistical Heterogeneity

Statistical heterogeneity was present in all of the patency analyses. The I^2 statistic was above 85% for most reported patency rates, indicating substantial heterogeneity. Only for primary assisted patency (which had the fewest number of studies) was I^2 in a range that is often considered to indicate moderate levels of heterogeneity (Supplemental Tables 1–4). The forest plots (Figures 2 and 3, Supplemental Figure 6) reflect this heterogeneity in study outcomes across the 32 publications. Figures 2 and 3 and Supplemental Figure 6 show the mean secondary patencies, with 95% CIs, at 12, 18, and 24 months. The wide variability in outcomes is clear, with differences in the 95% CIs of secondary patency between studies approaching 60% in some cases.

In order to summarize patency outcomes from the 32 studies, we generated aggregated Kaplan–Meier curves for primary, primary-assisted, and secondary patency. Calculation of aggregated Kaplan–Meier curves was weighted by

Table 1. Summary results of meta-analyses of patency rates in expanded polytetrafluoroethylene arteriovenous grafts

Follow-Up Period	Patency Measure	Study Arms	Number of ePTFE Accesses	Patency Rate (%)	95% CI	I^2 (P Value)
6 mo	Primary	30	2788	56	51 to 62	89 (<0.001)
	Primary-assisted	14	1281	59	52 to 67	88 (<0.001)
	Secondary	25	2126	80	75 to 84	88 (<0.001)
12 mo	Primary	31	2839	41	35 to 47	92 (<0.001)
	Primary-assisted	16	1404	46	41 to 51	74 (<0.001)
	Secondary	32	2555	70	64 to 75	91 (<0.001)
18 mo	Primary	21	1700	34	27 to 41	92 (<0.001)
	Primary-assisted	10	1050	39	34 to 45	70 (<0.001)
	Secondary	22	1871	59	53 to 65	88 (<0.001)
24 mo	Primary	22	1733	28	22 to 33	89 (<0.001)
	Primary-assisted	12	1232	34	29 to 39	68 (<0.001)
	Secondary	24	2053	54	47 to 61	92 (<0.001)

95% CI, 95% confidence interval; ePTFE, expanded polytetrafluoroethylene arteriovenous grafts.

the number of patients in each study. These curves, on the basis of all included data, illustrate trends in primary, primary-assisted, and secondary patency (Figure 4). Error bars indicate 95% CIs for patencies at 6, 12, 18, and 24 months. Although CIs for primary and primary-assisted patency overlap at each time point, secondary patency clearly separates from primary and primary-assisted patency, and its 95% CI for secondary patency does not overlap with other patency rates. The width of the secondary patency CI at 6 months was 9% (75% to 84%), whereas at 24 months was 14% (49% to 63%).

Infections

Infection rates could be analyzed in 14 studies, contributing 17 study arms and 1418 access placements, and representing 44% of all included studies and 42% of ePTFE graft placements. Definitions of reported infections varied substantially, and included descriptions of site infections, infections requiring hospitalization, and infections requiring graft excision. These varying definitions of "graft infection" substantially complicated the aggregate interpretation. In addition, most studies that did report infections did so as a proportion of patients experiencing infections over the entire study period, rather than as the rate of infections per patient-year. Infection rates on a per-patient-per-year basis could be estimated from some reports, but there was some uncertainty in such calculations, because often only mean follow-up periods were reported. Nonetheless, because it is important to gain a full understanding of ePTFE infectious complications, we calculated infections based upon total numbers of reported infections and, in several cases, the mean follow-up period for the study. This gave an overall annual infection rate of 9% per patient-year (Figure 5).

Stratified Analyses

Stratified analyses of secondary patency identified some differences in patency rates across studies of differing types. These are summarized in Figure 6, with full forest plots provided in Supplemental Figures 5-21. Studies conducted within the US had lower secondary patency rates at both 12 and 24 months as compared with ex-US studies. Standard ePTFE grafts had lower mean secondary patencies than those study arms including concomitant drug therapy (*e.g.*, dipyridamole) or involving hybrid grafts (*e.g.*, cuffed grafts). Notably, the difference between secondary patency rates in retrospective studies versus those in prospective controlled trials exhibited the largest differentials in these strata, with prospective controlled trials reporting higher secondary patency rates than retrospective or noncontrolled trials. This may indicate that the patient care patterns and intensities of follow-up utilized during prospective, randomized controlled trials may differ from the "real-world" care patterns that are typical for dialysis access. Hence, the overall better outcomes observed in randomized controlled trials may not be reflective of typical clinical practice and outcomes of hemodialysis patients.

Regarding sex effects, there was little difference in secondary patency for studies with below-average versus above-average proportions of participants who were men. Secondary patency rates tended to be higher in studies with above-average proportions of participants who were Black, which may be in conflict with preconceptions held by some investigators. However, consistent with other literature reports, patency rates tended to be better when patient cohorts contained below-average proportions of diabetics. Higher secondary patency rates were also found in studies that were scored as having lower risk of bias, and those that had no industry funding.

Funnel plots were created to investigate potential publication bias across included studies (Supplemental Figure 22). There was some evidence of publication bias, as reflected in asymmetry of the funnel plots at 12 and 24 months. However, the apparent direction of potential bias was in opposite directions for the funnel plots for secondary patency at 12 and 24 months, implying that there was little systemic publication bias in this sample of reports. The funnel plots likely reflect the high degree of heterogeneity found in the studies, as well as the low likelihood of very high or very low patency rates that might have "balanced" the funnel plots, as opposed to systematic publication bias.

Discussion

We conducted a systematic review of recent studies, spanning 2007 to 2019, reporting the patency of ePTFE grafts that are used for dialysis. In order to identify the

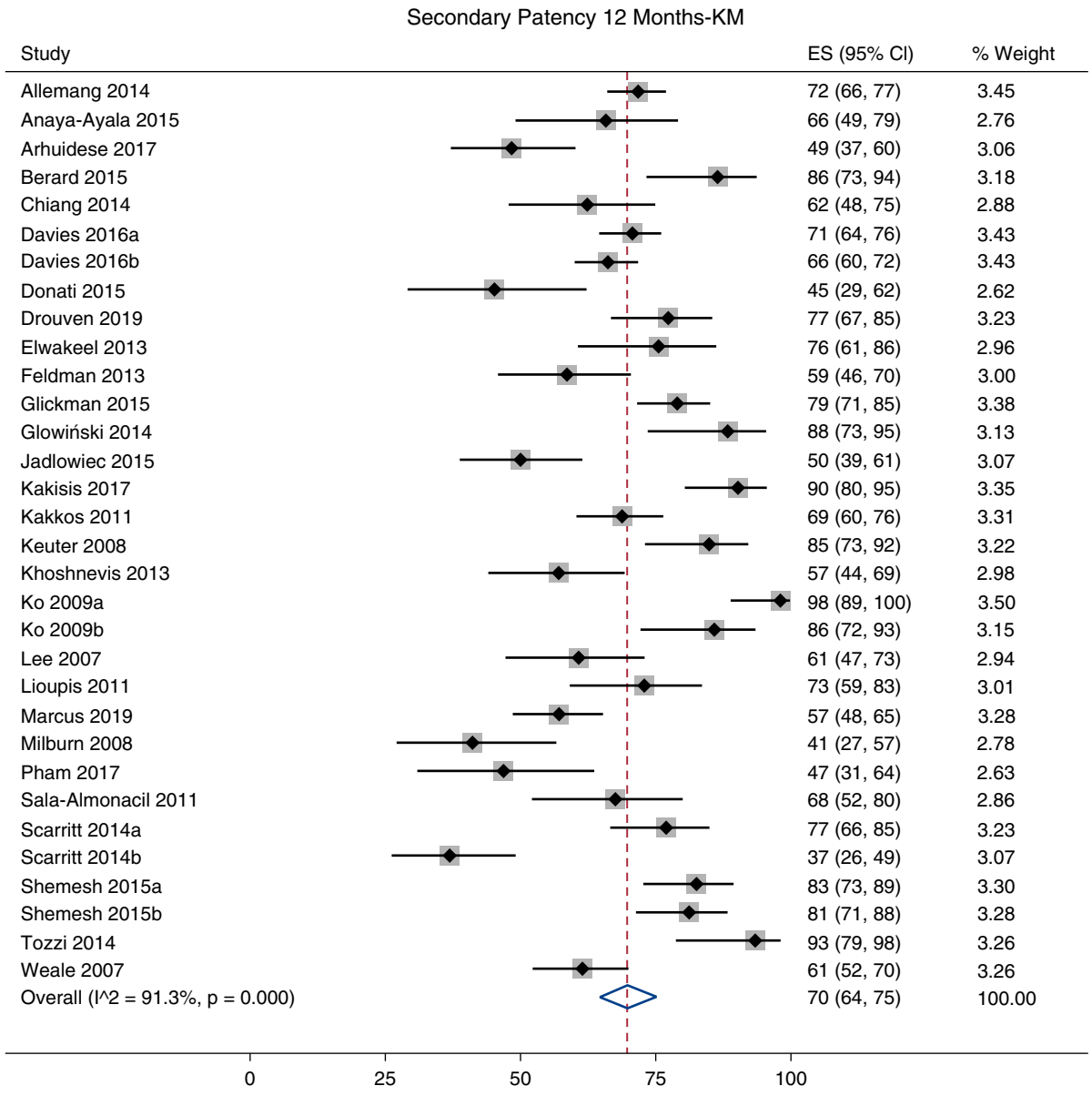

Figure 2. | **Forest plot of secondary patency at 12 months.** 95% CI, 95% confidence interval; ES, effect size; KM, Kaplan–Meier.

most current data, we limited our review to patients treated in the last 20 years. To avoid smaller studies with unstable estimates, we included study arms with at least 30 patients with ePTFE grafts. Because we anticipated the existence of relatively few randomized clinical trials, we included observational studies in this meta-analysis in order to provide a broader cross-section of publications and clinical experience. We believe the data presented here represent estimates of the highest quality available for AVG patency in the modern era, and reflect current trends in dialysis access placement and management.

Our results are generally consistent with those reported by other systematic reviews, albeit with slightly improved patency rates as compared with much older studies. Using data from 1966 to 2001, Huber *et al.* (4) reported primary patency rates for ePTFE grafts of 58% at 6 months and 33% at 18 months (versus 56% and 39%, respectively, in our study). Huber also reported secondary patency of 76% at 6 months (versus 80% in this analysis) and 55% at 18 months (versus 59% in this analysis). In a recent meta-analysis of mixed graft types published in 2016, Almasri *et al.* (49) reported primary patency rates of 40% at 2 years (versus 28% in this report) and secondary patency of 60% at 2 years (versus 54% in this report). In a systematic review of early cannulation grafts, Al Shakarchi and Inston (50) reported 12-month primary and secondary patency for Flixene grafts (Maquet) of 43.3% and 73.4% (versus 41% and 70% in this analysis, respectively). The same study reported 12-month primary and secondary patency for Acuseal grafts (Gore) of 43.6% and 70.5%. Hence, the results from this systematic analysis of ePTFE studies are generally in line with reports of other graft types that have been published in recent years.

In the last few decades, various improvements have been made in ePTFE grafts for hemodialysis access, including

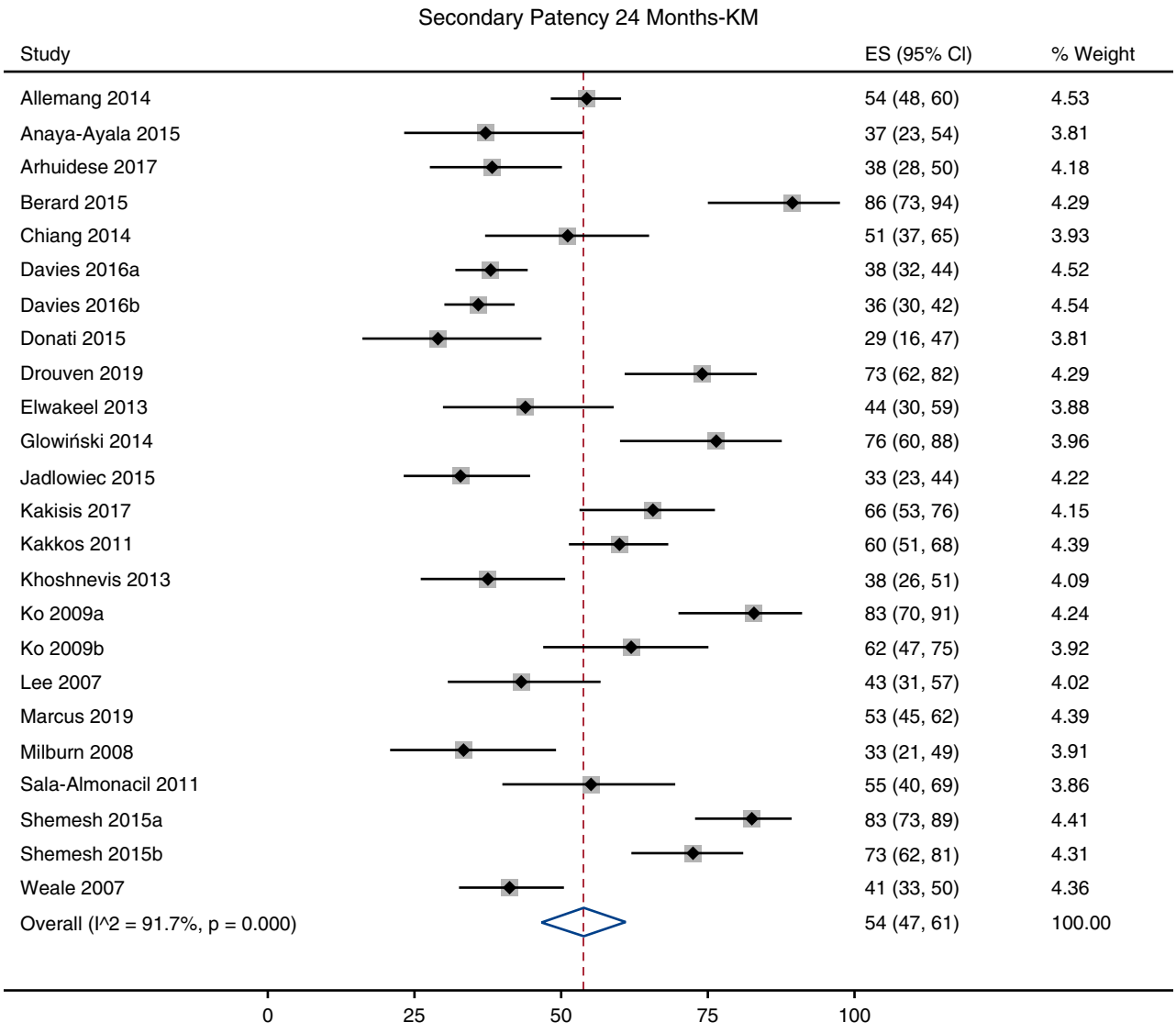

Figure 3. | **Forest plot of secondary patency at 24 months.**

covalent heparin bonding on the luminal surface and the introduction of self-sealing technologies to help enable early cannulation (28,46). Furthermore, technologies for covered stent deployment, drug-eluting stents, and drug-eluting balloons have become part of routine clinical practice in the care of vascular access (51,52). As the life expectancy of dialysis patients has increased from 3 to 5 years or more (53), there is an increased focus on access durability and functional secondary patency, as opposed to just primary patency. Advances in mechanical and pharmacologic thrombolytic techniques, and the proliferation of access centers that can treat malfunctioning access grafts, mean that transient access thrombosis is no longer a substantial barrier to patient well-being. In contrast, abandonment of a dialysis access conduit, or loss of secondary patency, forces the placement of an indwelling catheter and often the creation of a new surgical access. Our meta-analysis indicates that, on average, 20% of ePTFE grafts are abandoned at 6 months after implantation and 30% are abandoned by 1 year. By 2 years, nearly one half of all ePTFE grafts have failed and replacement has been required in order for the patient to remain on hemodialysis. Therefore, despite the proliferation of minimally invasive treatments and thrombolysis, and despite advances in angioplasty balloons, drug-coated balloons, and stenting options, ePTFE AVG secondary patency rates remain quite low, as compared with the patency of ePTFE vascular grafts in other anatomic locations (54,55). Nearly one in two patients receiving a ePTFE graft for hemodialysis access will require another graft, or another form of access, within 2 years.

As part of this review, we collected information on AVG complications, including infections, interventions, and steal. Of these, only infectious complications had information of sufficient quality to allow a statistical summary. In contrast, reports of steal and interventions were spotty across the various studies, and the modes of reporting were too highly variable to allow objective comparisons. Closer adherence to the publication guidelines of the

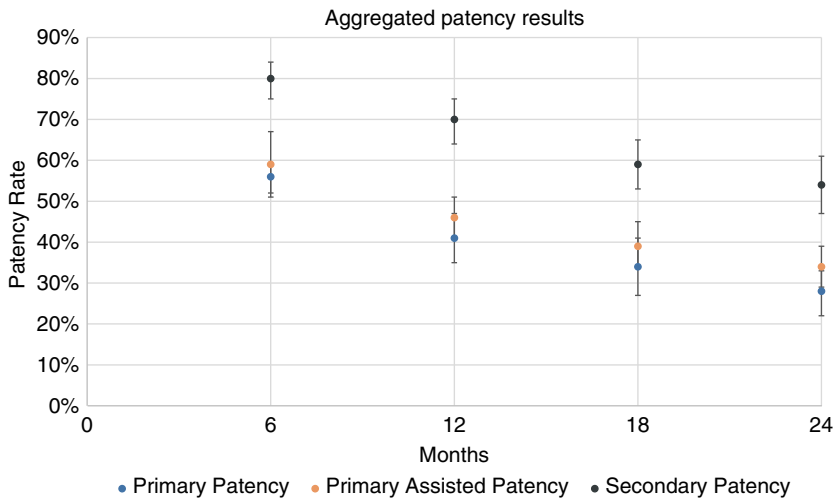

Figure 4. | **Aggregate Kaplan–Meier curves for primary, primary assisted, and secondary patency.**

Society for Vascular Surgery and the American Association for Vascular Surgery (10) would facilitate comparisons across studies in the future.

The overall rate of ePTFE graft infections was 9% per patient-year in this analysis. The rate of ePTFE infection is important because sepsis accounts for 9.3% of hospital

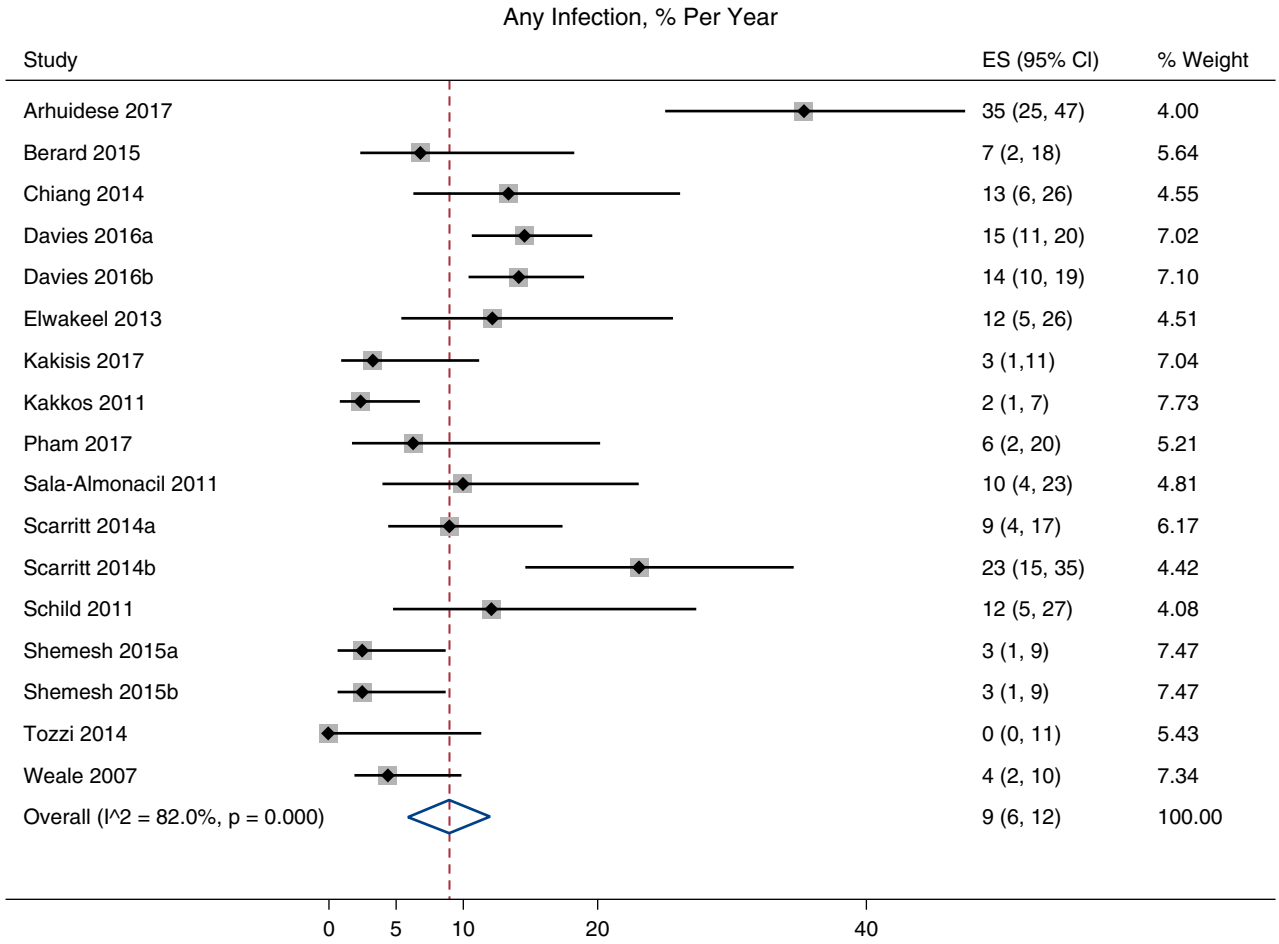

Figure 5. | **Forest plot of infection rate per patient per year.**

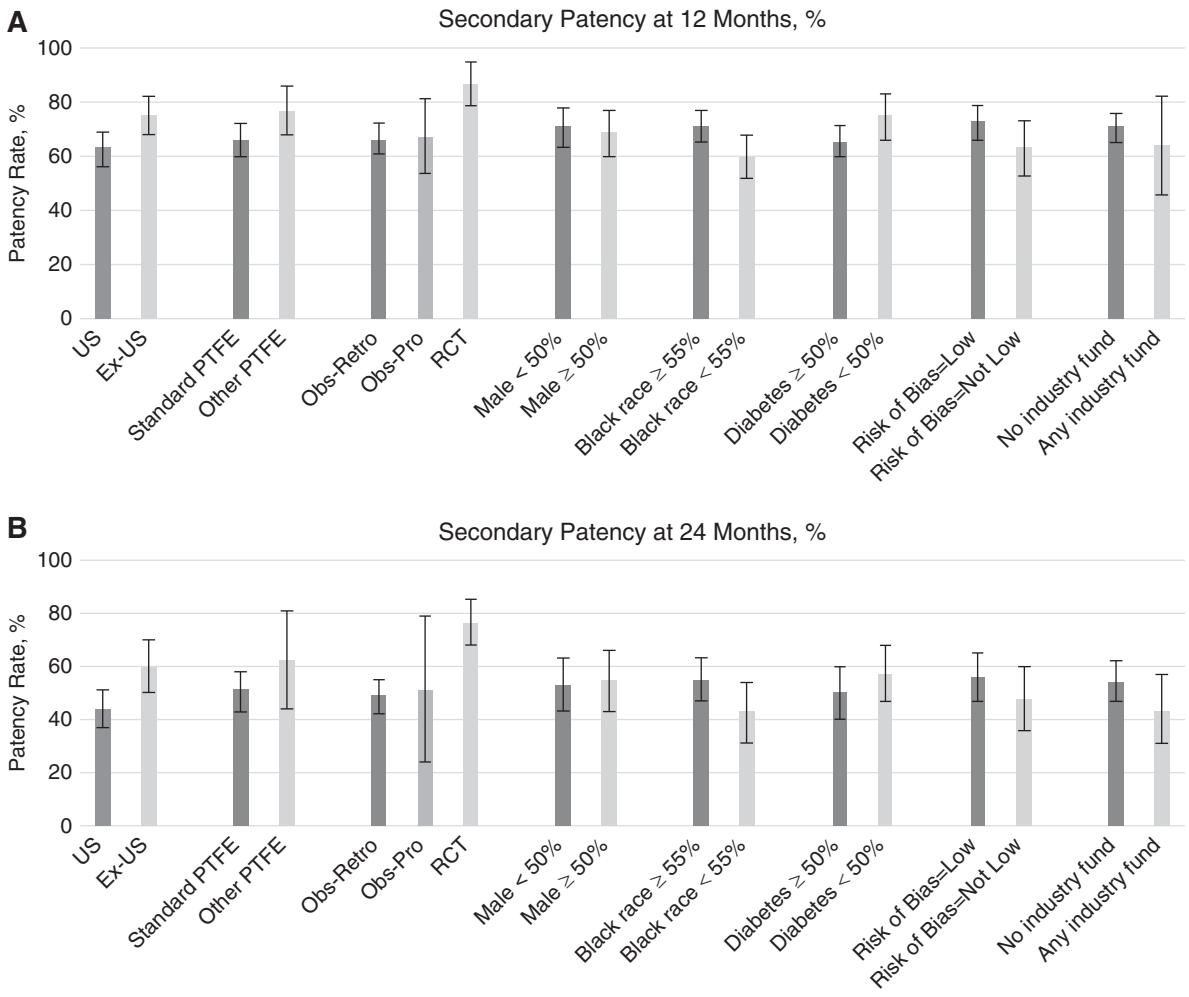

Figure 6. | **Subgroup meta-analyses of secondary patency at 12 and 24 months.** Obs-Pro, observational prospective; Obs-Retro, observational retrospective; RCT, randomized controlled trial.

admissions, and complications of dialysis access conduits drive 9.2% of hospital admissions in dialysis patients, with a total spending of $5–6 billion per year. The total number of hospitalizations for infections of hemodialysis access is approximately 58,000 per year in the US alone (56). Infection also leads to death in dialysis patients. Sepsis accounts for roughly 8% of deaths in hemodialysis patients in the US each year (56). Of the approximately 78,000 annual deaths of hemodialysis patients, 8%, or 6000 patients per year, die from sepsis.

Although fistulas are currently the gold standard for dialysis access, in part because of their low infection rates, certain subgroups of dialysis patients are burdened with higher use of ePTFE grafts and catheters. According to the United States Renal Data System database, ESKD patients who are women have lower rates of fistula use, and higher rates of ePTFE graft and catheter use, than do men (56). Women may be poorer candidates for fistulas than men, in part due to their smaller venous anatomy, making fistula maturation more technically challenging in women (57,58). United States Renal Data System data show that, at 1 year after dialysis initiation, the rate of fistula use is only 56% for women, as compared with 71% for men. Correspondingly, ePTFE use is higher: 20% of prevalent dialysis patients are women versus 12% of men. The rate of hospitalization for vascular access infection for women is 15% per patient-year, whereas for men it is 11% per patient-year. This may, at least in part, reflect infections related to ePTFE AVG use. The observed rate of 9% infection per patient-year is consistent with other data sources pointing to worsened infectious outcomes in patients, especially women, who utilize ePTFE grafts for dialysis.

As with all systematic reviews, our results are limited by the quality and characteristics of the included studies. There was significant statistical heterogeneity in our results, which was not well explained by differences in the variables we collected, but is not entirely unexpected given the predominance of observational data in our reviews. This heterogeneity likely has many sources, including variability in patient selection, and surgical and interventional approaches, given the range of study designs, patient cohorts, and geographic locations of the publications included in this analysis. Of note, randomized trials had the lowest heterogeneity in our analyses, and also the highest patency rates overall. These trials are likely more selective in their patient selection and provide more consistent follow-up. Unfortunately,

missing data for potentially explanatory variables (as shown in Supplemental Table 3) make it difficult to definitively explain heterogeneity in this collection of studies.

This meta-analysis provides an up-to-date estimate of the performance of ePTFE AVGs, within the context of improved graft designs and improved interventional techniques. In the era of "fistula first," which has been widely operative during the past 10–15 years, this analysis provides a summary of the functionality and infection rates for ePTFE when used as an access for hemodialysis.

Disclosures

R.J. Halbert, G. Nicholson, and R.J. Nordyke were employees of Beta6 Consulting Group at the time of this study, which received a grant from Humacyte. L.E. Niklason is a founder and shareholder in Humacyte, Inc., which is a regenerative medicine company. Humacyte, Inc. produces engineered blood vessels from allogeneic smooth muscle cells for vascular surgery. L.E. Niklason's spouse has equity in Humacyte, Inc., and L.E. Niklason serves on Humacyte, Inc.'s Board of Directors. L.E. Niklason is an inventor on patents that are licensed to Humacyte, Inc. and that produce royalties for L.E. Niklason. L.E. Niklason has received an unrestricted research gift to support research in her laboratory at Yale. A. Pilgrim is a former employee and a stockholder of Humacyte, Inc.

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Author Contributions

R.J. Halbert, G. Nicholson, and R. Nordyke were responsible for formal analysis, methodology, and writing the original draft; and all authors were responsible for conceptualization and reviewing and editing the manuscript.

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