Outcomes of early cannulation arteriovenous graft versus PTFE arteriovenous graft in hemodialysis patients: a meta-analysis and systematic review

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Review

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Abstract

Arteriovenous graft (AVG) is an alternative for hemodialysis (HD) patients with end-stage renal disease when their permanent vascular accesses fail. Since the last decades, the most widely used materials in these patients have been polytetrafluoroethylene (PTFE)-AVGs. Recently, several studies have reported that early cannulation (EC)-AVG can be an alternative to PTFE-AVG. This systematic review and meta-analysis aimed to compare the outcomes of EC-AVG and PTFE-AVG in HD patients. We searched the Ovid Embase, Ovid MEDLINE, and Cochrane Central Register of Controlled Trials for the relevant studies published from 01.01.2000 to 19.12.2022 by keywords and free words. All randomized controlled trials (RCTs) and observational cohort studies comparing EC-AVG with PTFE-AVG were included. Ten studies were included in analysis: one RCT, six retrospective cohort studies, and three prospective cohort studies. The results showed shorter cannulation intervals (four studies, 1116 participants: mean difference −23.62 days, 95% CI [−32.03, −15.21], $p < 0.05$) and less central venous catheter (CVC) usage (four studies, 733 participants: OR 0.20, 95% CI [0.04, 0.92], $p < 0.05$) for EC-AVG compared with PTFE-AVG, while comparable outcomes of primary patency (eight studies, 1712 participants: HR 0.89, 95% CI [0.70, 1.12]), primary assisted patency (five studies, 1355 participants: HR 1.13, 95% CI [0.70, 1.84]), secondary patency (nine studies, 1920 participants: HR 0.93, 95% CI [0.66, 1.31]), and infection risk (four studies, 640 participants: HR 1.12, 95% CI [0.48, 2.58]). When compared to PTFE-AVG in HD patients, EC-AVG seems to exhibit shorter cannulation intervals, less CVC usage, and comparable outcomes of graft patency, and infection risk.

Keywords

Prosthetic grafts, early cannulation graft, polytetrafluoroethylene, vascular access, patency

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Introduction

Autogenous arteriovenous fistula (AVF) is regarded as the first option for vascular access (VA) in hemodialysis (HD) patients with end-stage renal disease (ESRD), while arteriovenous graft (AVG) has been referred to an alternative when AVF has failed and/or vascular resources have been exhausted. Polytetrafluoroethylene (PTFE)-AVG is a conventional choice with reasonable primary and secondary patency rates, but reportedly higher infection and mortality rates than AVF.[1] However, whether these outcomes may be the fault of the AVG or result from a selection bias in the

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patients' cohorts that are selected for the prosthetic option, remains a matter for debate. Indeed, a central venous catheter (CVC) is probably needed for the first 2–3 weeks after implanting the PTFE-AVG, which may increase the subsequent risk of infection.[2]

Recently, a new material can be used for AVG after a short time delay. Early cannulation (EC)-AVG is a trilayer prosthetic graft with an elastomeric membrane that allows cannulation in 24–72 h after implantation. A shorter cannulation interval could decrease or avoid the use of CVC and prevent or reduce the risk of infection.[3] Though early cannulation could lead to a higher risk of AVF failure,[4] for EC-AVG, shorter intervals may still achieve excellent clinical and HD-related outcomes. A prior meta-analysis with 19 EC-AVG related studies showed that 1-year pooled primary and secondary patency of EC-AVG ranged between 43.3%–63.7% and 70.5%–85%, respectively,[5] which is comparable with the reported outcomes for AVG.[1] However, the main limitation of this meta-analysis was the absence of cross-comparison with the AVG group; therefore, it still lacks evidence if EC-AVG could be a better or equal alternative to AVG in HD patients.

The objective of our study was to perform a meta-analysis and systematic review of AVG patency, infection risk, re-intervention, all-cause mortality, costs, and length of hospital stay for EC-AVG and PTFE-AVG in HD patients.

Methods

Study design

This systematic review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and was registered in the PROSPERO database (ID: CRD42022378621).[6] The following PICOS was used to define the study protocol:

- Population: HD patients with ESRD who need AVG.
- Intervention: EC-AVGs.
- Comparison: PTFE-AVGs.
- Outcomes: primary outcomes: patency (primary, primary assisted, secondary patency, defined as published in the original studies[7]), infection risk, all-cause mortality; secondary outcomes: re-intervention, costs, length of hospital stay.
- Study: randomized controlled trials (RCTs), and observational cohort studies.

Search strategy

We performed an electronic database search in the Ovid Embase, Ovid MEDLINE, and Cochrane Central Register of Controlled Trials for the studies from 01.01.2000 to 19.12.2022. Key words and free words composed the search and were reported in the Supplement Materials. The results obtained from the search were exported to EndNote (Thomson Reuters, Canada) for cataloging and deduplication.

Data extraction and quality assessment

The titles and abstracts of obtained studies were screened independently by two authors. The selection was based on PICOS, studies that did not meet the inclusion criteria were excluded, while studies reported relevant data were retained for full-text assessment. Data from studies that met the PICOS were extracted using standard extraction forms.

Two independent authors assessed the risk of bias and quality of the selected studies. The Newcastle-Ottawa Scale (NOS) was used for assessing the quality of observational cohort.[8] While the Cochrane Collaborations tool was used to assess the risk of bias in RCTs.[9]

Subgroup and sensitivity analyses

We quantified statistical heterogeneity by Cochran's Q test and I^2 statistic, $p < 0.05$ and $I^2 \geqslant 50\%$ were regarded as high heterogeneity. A random-effects model was to analyze pooled outcomes from the high heterogeneity studies. Subgroup analyses were conducted by EC-AVG brands. In sensitivity analyses, we excluded the RCT and studies with high bias (unknown cannulation interval, unreliable data, thigh AVG), and the meta-analysis was repeated to explore the influence of these factors on effect size.

Statistical analysis

Based on the Cochrane Handbook,[10] categorical variables were expressed as counts and percentages (*n*, %), and continuous variables as means ± standard deviation (mean-± SD), If studies reported concentrations as median and interquartile range (IQR), the corresponding mean and SD were estimated.[11]

To solve the problems of different follow-up times and censored data (died or lost follow-up), a log hazard scale was used for time-to-event outcomes.[12] The method described by Tierney et al.[13] was used to calculate log (HR) and variances when the studies directly reported hazard ratios (HR). For studies that published Kaplan-Meier (K-M) curves and survival tables, the methods described by Guyot et al.[14] were applied to individual time-to-event patient outcomes to assess log (HR) and variances. Pooled statistics were calculated by Review Manager 5.4.1, effect sizes were expressed as HRs, and the associated 95% confidence intervals (CI). Results were expressed as the odds ratio (OR) with 95% CI for dichotomous outcomes. Where continuous scales of measurement were used to assess the cannulation intervals, the mean difference (MD) was used.

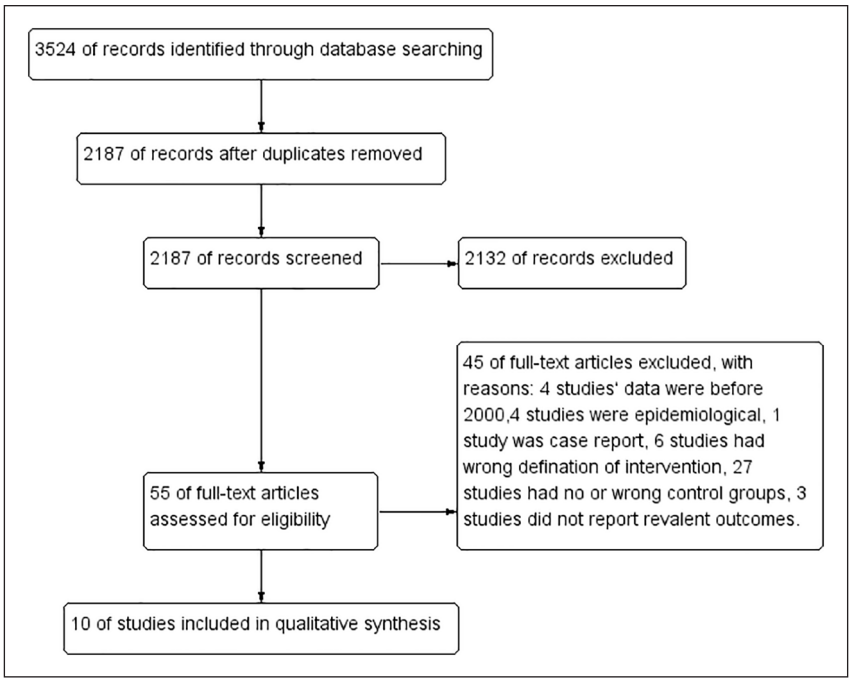

Figure 1. Flow diagram of searching results with inclusion and exclusion following screening and selection.

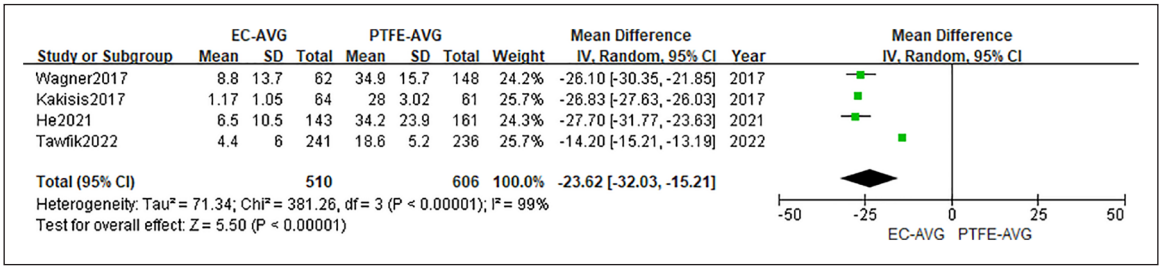

Figure 2. Mean difference of cannulation interval between EC-AVG and PTFE-AVG.

Analyses were based on previous published studies; thus, no ethical approval and patient consent are required.

Results

General overview and quality assessment

The electronic search (last queried: 19 December 2022) identified 3524 potential studies. 1337 studies were deduplicated and 2132 were excluded by screening titles and abstracts. Of the left 55 studies whose full text was reviewed, 45 of them were excluded for various reasons, as reported in Figure 1. Six retrospective cohort studies, three prospective cohort studies, and one RCT,[15–24] were finally selected for subsequent analyses which included 978 EC-AVG patients and 967 PTFE-AVG patients.

Characteristics of the 10 selected studies are shown in Supplement Materials Table 1. Maya2007, Kakisis2017, and Kakkos2011 used Vectra EC-AVGs; Scarritt2014 and Chiang2014 used Flixene EC-AVGs; Acuseal EC-AVGs were used by Giannikouris2018, Gerhardt2019, He2021, Tawfik2022, and 81% of the patients in Wagner2017. The grafts in control groups were (e)PTFE grafts from different companies. Seven studies reported the medium cannulation intervals and the majority of EC-AVGs were cannulated in 3 days (range: 2 h–19 days), and all the PTFE-AVGs were cannulated after 2 weeks (range: 14–52 days). Four studies could calculate the mean ± SD of cannulation interval; we compared its mean difference between EC-AVG and PTFE-AVG, and this was statistically significant (MD −23.62, 95% CI [−32.03, −15.21], $p < 0.01$, $I^2 = 99\%$, Figure 2).

Four studies, Scarritt2014, Wagner2017, He2021, and Tawfik2022, reporting CVC usage showed that EC-AVG patients had fewer chances for CVC than those who received PTFE-AVG (OR 0.20, 95% CI [0.04, 0.92], $p < 0.05$, $I^2 = 96\%$, Figure 3).

In terms of baseline characteristics, the patients of Chiang2014 from the PTFE-AVG group were younger than EC-AVG patients. In He2021, more patients from

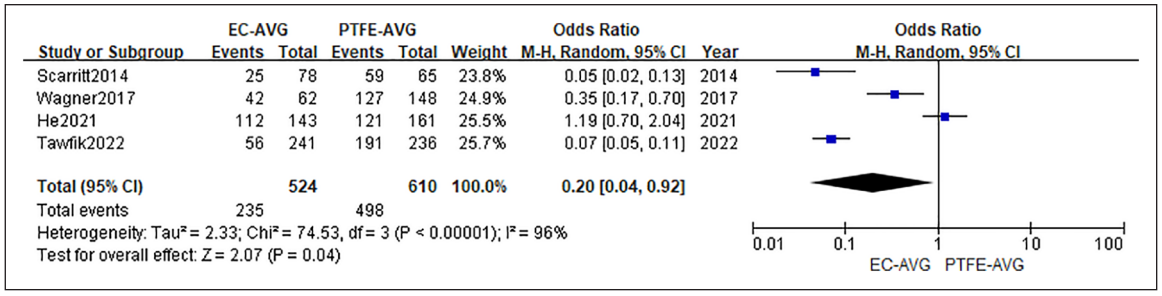

Figure 3. Odds ratio of CVC usage between EC-AVG and PTFE-AVG.

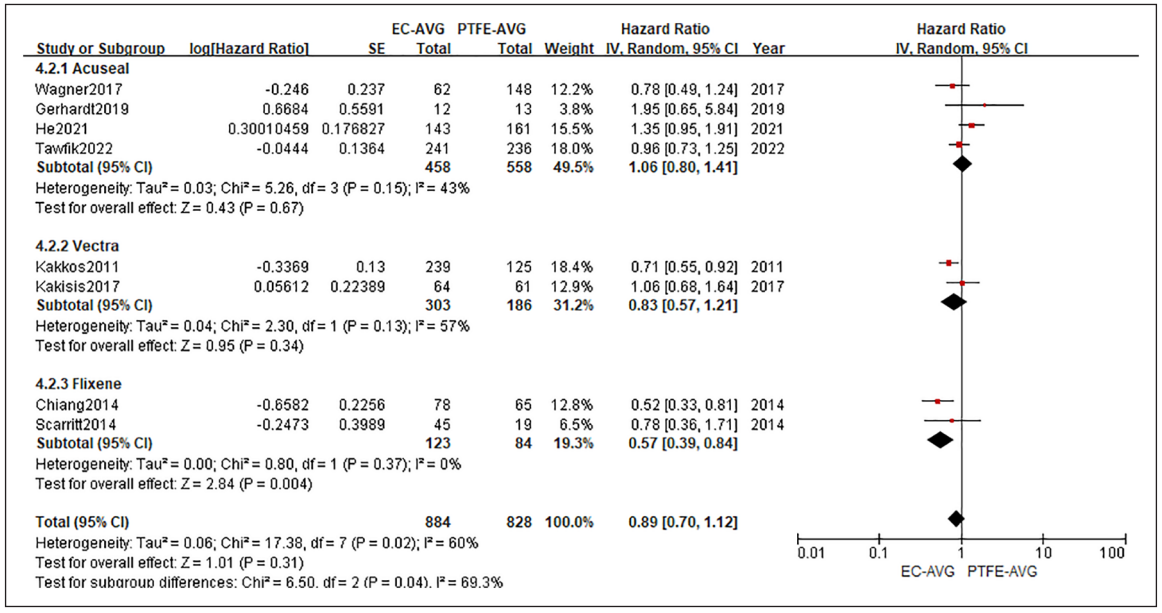

Figure 4. Hazard ratio of primary patency between EC-AVG and PTFE-AVG. Subgroup analysis was stratified based on EC-AVG brands.

EC-AVG group were under antiplatelet treatment than PTFE-AVG patients. No significant differences were detected in other baseline characteristics between two groups.

Regarding the quality of the included studies, Kakkos2011, Scarritt2014, and Gerhardt2019 did not report the cannulation interval, and were considered as high-risk for bias; Chiang2014, Scarritt2014 reported the K-M survival curves without patients risk number, based on the method described in Guyot et al.,[14] a lower quality of results was expected. The quality and bias assessment of all the studies is summarized in Supplement Materials Table 2.

Primary patency

Eight studies comprising 1712 patients (EC-AVG 884, PTFE-AVG 828) were included in this analysis, the pooled effect size of primary patency was not in favor of any graft type (HR 0.89, 95% CI [0.70, 1.12], $p=0.31$, $I^2=60\%$.) Subgroup analyses were stratified by the brands of EC-AVG, and the Flixene EC-AVG showed an HR 0.57, 95% CI [0.39, 0.84] when compared to other EC-AVG, as shown in Figure 4. Sensitivity analysis was performed by excluding one RCT, Tawfik2022, or three studies with unknown cannulation intervals, Kakkos2011, Scarritt2014, Gerhardt2019, or two low-quality studies, Chiang2014, Scarritt2014, which did not significantly alter the overall effect size, Supplement Materials Figure 1.

Primary assisted patency

Five studies comprising 1355 patients (EC-AVG 731, PTFE-AVG 624) were analyzed for primary assisted patency, and the pooled effect size was HR 1.13 (95% CI [0.70, 1.84], $p=0.62$, $I^2=89\%$), as shown in Figure 5. The number of studies was too small for subgroup analysis. Also, one RCT, Tawfik2022, or one low-quality studies, Chiang2014, were excluded for sensitivity analysis, and this

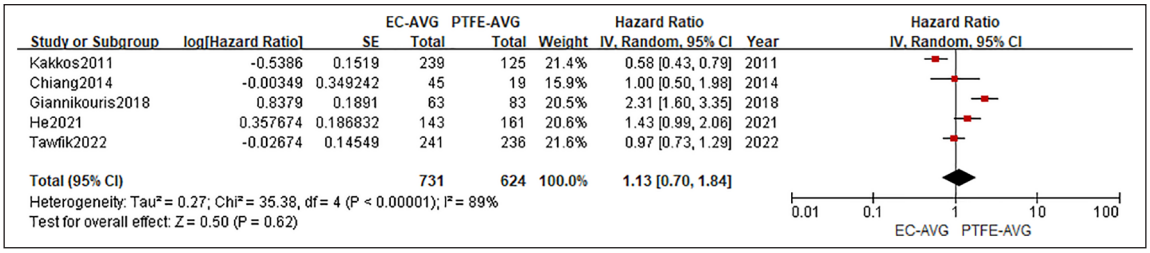

Figure 5. Hazard ratio of primary assisted patency between EC-AVG and PTFE-AVG.

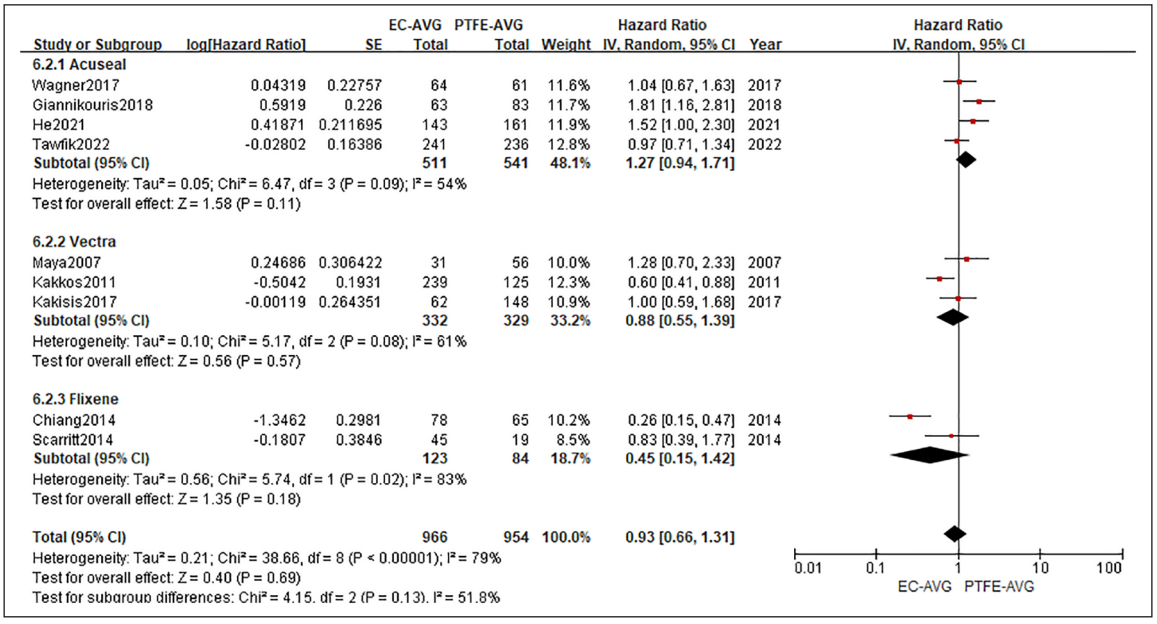

Figure 6. Hazard ratio of secondary patency between EC-AVG and PTFE-AVG. Subgroup analysis was stratified based on EC-AVG brands.

did not significantly alter the overall effect size, Supplement Materials Figure 2.

Secondary patency

Overall, 1920 participants (EC-AVG 966, PTFE-AVG 954) from nine studies were analyzed for secondary patency, the pooled effect size was HR 0.93 (95% CI [0.66, 1.31], $p=0.69$, $I^2=79\%$). The subgroup analysis showed a high heterogeneity, but the size effect of different brands did not have a significant difference, as indicated in Figure 6. Sensitivity analysis was carried out by excluding one RCT, Tawfik2022, or two studies with unknown cannulation interval, Kakkos2011, Scarritt2014, or two low-quality studies, Scarritt2014, Chiang2014, or one thigh AVG, Maya2007, but a significant change in the overall effect size was not reported, Supplement Materials Figure 3.

Infections

Four studies with 640 participants were included in the infection analysis, the pooled effect size was HR 1.12, 95% CI [0.48, 2.58], $p=0.79$, $I^2=59\%$, as shown in Figure 7. The included studies were not sufficient for subgroup analysis. In sensitivity analysis, one unknown cannulation interval study, Kakkos2011, or one low-quality study, Chiang2014, and one thigh AVG study, Maya 2007, were not included, but the overall effect size was not altered, Supplement Materials Figure 4.

Re-intervention

Two studies containing 210 participants reported the number of re-intervention procedures to maintain AVG patency. The main procedures used were angioplasty, patchplasty, thrombolysis, thrombectomy, and revision. Because of the various follow-up periods, we did not pool the combined results, and the number of procedures did not show any significant differences between EC-AVG and PTFE-AVG, as reported in Supplement Materials Table 3.

Mortality

Seven studies including 1294 patients were analyzed for mortality, and all the studies reported the death number in their follow-up periods. However, the follow-up periods

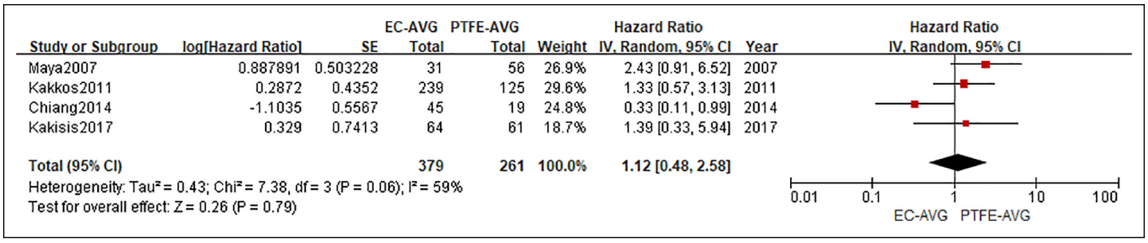

Figure 7. Hazard ratio of infection risk between EC-AVG and PTFE-AVG.

varied from 1 to 5 years, and no pooled size effect could be analyzed. We listed the mortality for each study, six of these studies showed a lower mortality in EC-AVG than PTFE-AVG, while one study showed a higher mortality in EC-AVG than PTFE-AVG, as shown in Supplement Materials Table 4.

Discussion

In this systematic review and meta-analysis, which encompassed 10 studies and over 1000 subjects, we compared the clinical outcomes of EC-AVG with PTFE-AVG in terms of patency, risk of infection, and mortality. Our analysis showed that the EC-AVG from different brands had comparable patency and infection-related outcomes with PTFE-AVG, but they could be cannulated earlier than PTFE-AVG, thereby decreasing the need or time of CVC use. Though previous meta-analyses have studied similar outcomes between different brands of EC-AVG, and indirectly showed that EC-AVG related safety and effectiveness were similar to PTFE-AVG, this is to the best of our knowledge the first meta-analysis in the literature with an attempt to directly compare the outcomes of EC-AVG with PTFE-AVG.

PTFE-AVG are most used as an alternative access option when no native vascular resources are still viable to establish a new AVF. As a synthetic vessel, PTFE-AVG has reasonable primary and secondary patency, as demonstrated in the available literature.[1] However, the PTFE-AVG needs at least 2–3 weeks to achieve maturation before the initial cannulation. During this period, the PTFE-AVG heals with the surrounding tissue to prevent leakage, infection, and thrombosis.[25,26] Therefore, CVC is almost always needed to transit this period for patients on maintenance HD, which may increase the risk of infection.[27] Similarly, ESRD patients who needs to start urgently with hemodialysis, are usually managed with a CVC if a pre-existing AVF/AVG is unavailable. In this sense, the main clinical advantage of EC-AVG may reside in the possibility to be punctured within 24–72 h post-operatively, thereby reducing the need and/or time of using a CVC. Indeed, in seven out of the 10 studies included in our meta-analysis, the cannulation intervals of EC-AVG were less than that for PTFE-AVG.

Our meta-analysis showed that EC-AVG had comparable patency to PTFE-AVG, which remains an important concern for any long-term HD access. Lin et al.[28] compared the functional cumulative survival of PTFE-AVG cannulated in 30 days with the ones cannulated between 31 and 90 days, results showed that early cannulation of PTFE-AVG led to poorer outcomes. In our study, cannulation intervals of EC-AVG were significantly shorter than PTFE-AVG, but we did not find that earlier cannulation led to a higher risk of primary, primary assisted, and secondary patency failure than PTFE-AVG. As the pooled effect size had a high heterogeneity, and the recent meta-analysis of EC-AVG reported that brands of EC-AVG might relate to patency rates,[5] we performed a subgroup analysis based on brands. The results showed no significant difference in secondary patency by brand, although primary assisted patency was not analyzed because of the small number of studies. In terms of primary patency, the Flixene graft showed a lower risk of failure, but the analysis only included two studies with a small number of patients, and both articles had bias in data extraction due to the lack of risk number, so whether Flixene has better outcomes needs to be supported by more evidence.

Endovascular intervention is a prevalent therapy option to maintain patency in EC-AVG and PTFE-AVG. Neointimal hyperplasia, inward remodeling, cannulation injury, and thrombosis are the most common factors which may cause AVG dysfunction, and different interventional therapies are used to maintain the patency of AVG.[29–32] Two of our included studies reported outcomes of secondary procedures, and EC-AVG did not show the significant benefits of re-intervention.

In the present work, EC-AVG and PTFE-AVG seemed to entail a similar infection risk, although EC-AVG might have a better survival outcome than PTFE-AVG. Due to the immunocompromised state often witnessed in ESRD patients, repeated cannulation of PTFE-AVG can lead to a rise in infection rates up to 20%–35%.[33,34] Since EC-AVG had a shorter cannulation interval than the PTFE-AVG, which may entail less time for complete tissue healing and graft incorporation, it could be at higher risk for the development of infectious events. Nevertheless, the pooled effect size in our meta-analysis showed a similar infection risk for EC-AVG as for PTFE-AVG. Regarding mortality,

seven articles reported the occurrence of death during the follow-up period, but the follow-up time varied from 1 to 5 years, thereby hindering perform a meaningful meta-analysis. By the currently listed results, six articles reported lower mortality of EC-AVG than PTFE-AVG, and only one study reported the opposite result. Though EC-AVG might reduce mortality by decreasing CVC use and preventing infection, more high-quality RCTs or prospective studies are needed to elucidate this point.

Study limitations

Firstly, the patency of AVG can be affected by many factors, and the type of AVG is one of them. Owing to limited data from observational studies, we could not perform any subgroup analysis based on other factors. RCTs with clear case-mix can overcome the weakness of the available evidence and provide a brief explanation of the differing case-mixes of the compared data. Secondly, the included studies have spanned over a long period of time, and some outcomes like infection may differ between recent studies versus older ones. Thirdly, the cost and the length of hospital stay between EC-AVG and PTFE-AVG were not analyzed as no available data could be extracted from included studies. Fourthly, corresponding authors of studies with missing data were contacted to retrieve missing information, however, we could not obtain more additional information.

Conclusions

The current evidence from our systematic review and meta-analysis revealed that EC-AVG could be cannulated in 72 h and reduce CVC usage while maintaining similar patency and infection risk when compared with PTFE-AVG. Whether EC-AVG had lower mortality than PTFE-AVG, or whether different brands of EC-AVG had various outcomes remains to be determined in future studies.

Declaration of conflicting interests

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Supplemental material

Supplemental material for this article is available online.

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