

SYSTEMATIC REVIEW

Short Term Success of Treatments to Salvage Thrombosed or Failing Synthetic Arteriovenous Grafts in End Stage Renal Disease: A Systematic Review and Network Meta-Analysis of Randomised Controlled Trials

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WHAT THIS PAPER ADDS

This article used network meta-analysis to indirectly estimate differences between treatments to salvage thrombosed/failing synthetic arteriovenous grafts in end stage renal disease that have not been compared head to head. The synthesis of existing evidence showed that stent grafts perform better than balloon angioplasty in decreasing the failure risk at three months. The drug eluting balloon was ranked high as the best treatment, but the evidence stems from one small study and most comparative effect estimates were not statistically significant.

Objective: There is currently uncertainty regarding the ideal treatment to salvage thrombosed or failing synthetic arteriovenous grafts (AVGs) in patients with end stage renal disease. Therefore, a systematic review up to December 2018 and network meta-analysis of randomised control trials (RCTs) that compared three month failure risk of available treatments was carried out.

Methods: Medline, Scopus, Embase, and the Cochrane Library were the data sources. Pairwise meta-analyses were based on random effects models. Network meta-analysis was conducted within a frequentist framework with a multivariable random effects approach to model treatment effects across studies. The metric of choice was the odds ratio (OR) along with the associated 95% confidence interval (CI).

Results: Sixteen two arm RCTs were included involving 2011 patients who were randomised to six different treatments (plain balloon angioplasty, open surgical repair, stents, stent grafts, drug eluting balloons (DEBs), and cutting balloons). The network of RCTs had a star like geometry with plain balloon angioplasty being the common comparator. There were no significant differences between treatments with regards to risk of failure at three months with the exception of stent graft use that significantly reduced the risk of failure compared with plain balloon angioplasty (OR 0.53, 95% CI 0.34–0.84). Based on surface under the cumulative ranking curve (SUCRA) values, the best interventions to salvage thrombosed or failing AVGs were DEB and stent grafts.

Conclusions: Stent graft seems to perform better than plain balloon angioplasty in terms of saving thrombosed or failing AVGs. However, this network meta-analysis was limited by the lack of closed loops and thus unable to assess consistency between direct and indirect evidence. The efficacy of DEBs as a promising treatment deserves further investigation and new RCTs are required.

Keywords: Arteriovenous graft, End stage renal disease, Network meta-analysis, Vascular access

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INTRODUCTION

The natural history of synthetic arteriovenous grafts (AVGs) in patients with end stage renal disease is to fail sometime after their creation because of neo-intimal stenosis at the venous anastomosis. Thrombectomy/thrombolysis as a standalone procedure in the majority of cases is inadequate

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because it does not solve the underlying stenosis problem. This underlying stenosis, responsible for the majority of graft failures, can be corrected either by open surgery (patch angioplasty, jump grafts) or by endovascular means.¹ The European Vascular Access guidelines recommend plain balloon angioplasty (BA) for the treatment of venous outflow stenosis.² However, recent randomised controlled trials (RCTs) support stent graft (SG) use as the first choice treatment,^{3–6} while a wide spectrum of other endovascular treatments and techniques including bare stents (STs), cutting balloons (CBs), and drug eluting balloons (DEBs) also have been used, with mixed results.

There is currently uncertainty regarding the ideal treatment to salvage thrombosed or failing synthetic AVGs. Therefore, a systematic review and network meta-analysis (NMA) of RCTs was performed to simultaneously compare the efficacy of available treatments. A useful summary of existing evidence that can be used to facilitate clinical decision making is provided.

MATERIALS AND METHODS

This work was registered in the International Prospective Register for Systematic Reviews (PROSPERO registration number: CRD42019116081). The results are presented following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension statement for network meta-analyses.⁷

Data sources and searches

Medline (via PubMed), Scopus, and Embase were searched independently by two authors (A.I.Y., C.A.) for articles published up to December 2018 without language or publication date restrictions. The terms used for the search were carefully and particularly selected to identify eligible reports. Medical Subject Headings (MeSH), Boolean search operators, and limits in each database were adapted accordingly. The searching algorithm included the following terms: (“vascular access graft” OR “arteriovenous graft”) AND (“thrombosis” OR “surgical repair” OR “balloon angioplasty” OR “covered stent” OR “stent graft” OR “endovascular repair” OR “failing graft”). The search in the Cochrane Library was subsidiary to ensure that the primary search in the three, above mentioned electronic databases did not miss any eligible study.

Two authors (A.I.Y. and C.A.) independently screened titles and abstracts, and carefully read the full texts of the selected articles to examine their eligibility. The reference lists of the selected articles and of relevant systematic reviews were scrutinised to retrieve other eligible trials.

Eligibility criteria

Studies were considered eligible if (i) they were RCTs, (ii) they compared treatments for thrombosed or failing synthetic AVGs including open surgical revision of the venous anastomosis, BA, stenting, SG insertion, or other endovascular treatment procedures, and (iii) provided patency data for each group at follow up (three months). Studies were

excluded if they did not deal with the underlying problem of venous outflow stenosis comparing only different thrombolysis devices in order to minimise conceptual heterogeneity across trials. The distribution of certain effect modifiers including patients’ age and gender, and the prevalence of diabetes was used to assess the transitivity assumption.

Data extraction and types of outcomes

Two authors (A.I.Y. and M.K.L.) independently abstracted the following data from each study: first author, journal and year of publication, study design and duration, setting, number of randomised participants, population and disease characteristics, outcome definitions, interventions, and number of patients with events in the two comparison groups.

The primary outcome assessed was risk of primary failure (no patency) at three months following a procedure to treat thrombosed or failing AVGs. If primary patency was not reported, assisted primary or secondary patency was used instead. Numbers of events in the comparison groups were obtained from text, tables, or survival curves in the eligible, published articles.

The risk of bias of the included studies was assessed using the Cochrane Collaboration tool, which evaluates the quality of studies in seven domains (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias), and can be expressed as low, unclear, or high. The assessment of risk of bias was done independently by two authors (C.A. and M.K.L.) using the RevMan Software 5.3 (The Cochrane Collaboration, Copenhagen, Denmark). CINeMA 1.1 software (University of Bern, Switzerland) was used to visualise the risk of bias in the map of network geometry.

Discrepancies in data abstraction and evaluation of risk of bias among reviewers were discussed and resolved with consensus.

Data synthesis and analysis

The odds ratio (OR) was the metric of choice to measure intervention effects (failure at three months) in all comparisons. Study level ORs with 95% confidence intervals (CIs) were computed based on the intention to treat principle. Pairwise meta-analyses (random effects models using the method of DerSimonian and Laird, with the estimate of heterogeneity taken from the Mantel–Haenszel fixed effect model) were carried out in STATA 14 (Stata Corp., College Station, TX, USA).^{8,9} Statistics for heterogeneity for all direct comparisons including tau-squared, Cochran’s Q, and *I*-squared (*I*²) were also computed.⁸ Publication bias or small study effects in pairwise meta-analyses were not assessed given the small number of studies (fewer than 10) included in each meta-analysis.^{8,10,11}

Network meta-analysis was conducted to compare all salvage procedures for thrombosed or failing AVGs.¹² NMA simultaneously assesses more than two interventions

combining direct and indirect evidence. For instance, for treatments A and B, direct evidence comes from head to head trials comparing A and B. Indirect evidence is based on one or more common comparators. For example, when studies that directly compare treatments A and B are lacking, their difference in efficacy or safety can be estimated by their direct comparison with treatment C.

NMA was conducted within a frequentist framework in STATA 14 using the network suite¹³ and other network related commands.^{14,15} A multivariable random effects meta-analysis modelled the intervention effects across studies and a network map was drawn.^{13,16–19} ORs and 95% CIs for all comparisons in pairs in the network were put in the off diagonal cells of a league table. The contribution of direct evidence to indirect estimates and to the whole network was also measured.^{14,20} The frequentist resampling method, with 10 000 bootstrap replicates, was used to estimate probabilities of each treatment being at a specific order, mean rank of treatments, and surface under the cumulative ranking area (SUCRA) values (the larger the SUCRA value, the better the treatment, i.e. more effective or safer).^{13,14,16,21}

Heterogeneity in NMA was estimated through the restricted maximum likelihood approach and was assumed to be constant across treatment contrasts (common tau squared).^{13,17} Predictive intervals that reflect the extent of heterogeneity in network meta-analytic effect estimates and in which future relative treatment effects are expected to lie were also estimated.^{14,15,22}

RESULTS

Findings of electronic search

The literature search resulted in 1893 records (Fig. 1). Following removal of duplicates and exclusions, 21 full text articles were read. Of these, five articles were excluded (two meta-analyses,^{23,24} two articles that did not include the necessary data to allow calculations,^{25,26} and one article²⁷ that referred to restenosis after stent placement). In total, 16 articles were selected for pairwise meta-analyses and NMA.^{3–6,28–39} These 16 two arm RCTs studied a total of 2011 patients randomised in six different treatments, i.e. plain BA ($n = 1034$), open surgery (S) ($n = 277$), stenting ($n = 85$), SGs ($n = 429$), CBs ($n = 173$), and DEBs ($n = 13$). More than half of the patients underwent plain BA, which was the common comparator in all studies. The publication dates ranged between 1987 and 2018. Differences in patients' age, gender, and diabetes prevalence among studies were within acceptable rates. Therefore, slight variation in these features was not likely to affect the transitivity assumption.

The characteristics of the included studies are shown in Tables 1 and 2.

Risk of bias in included studies

All of the included studies were very likely to suffer from bias in blinding of personnel as this is almost impossible in surgical procedures. There was some blinding of the outcome assessment in only two studies (12.5%). Eight studies (50%)

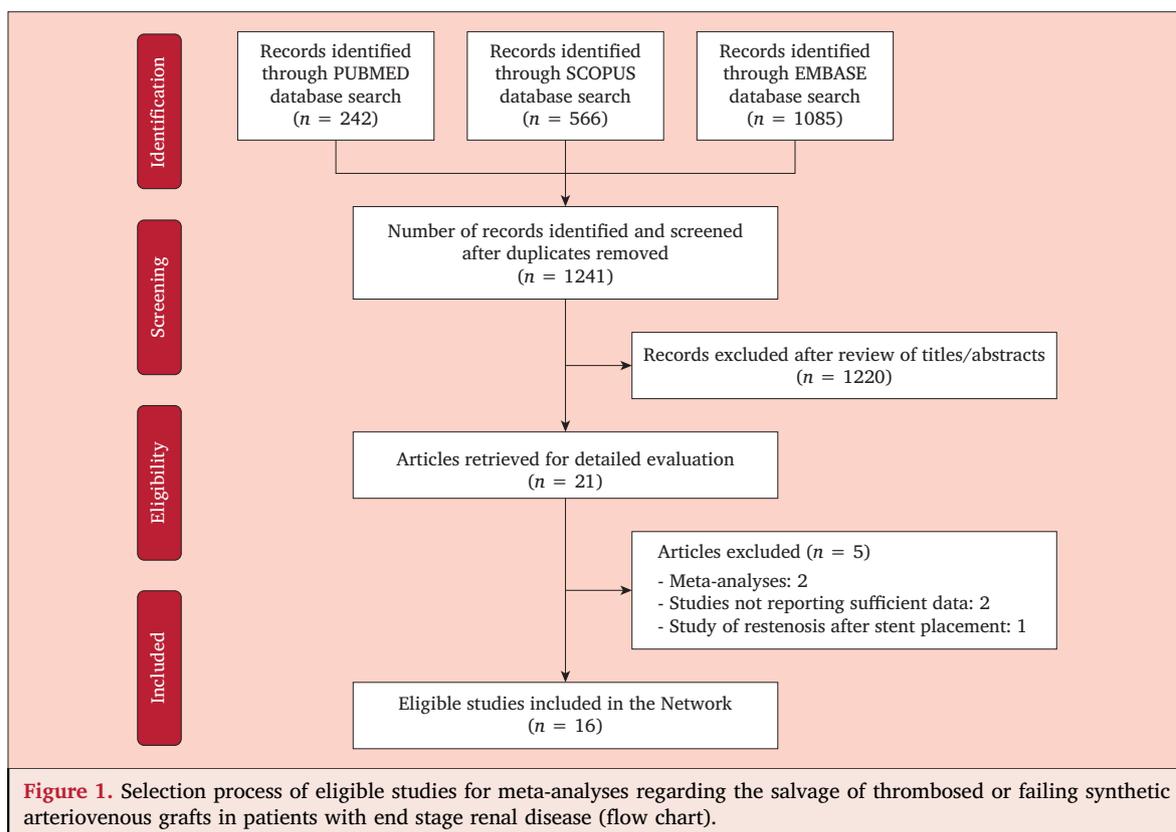


Table 1. Characteristics of the 16 randomised controlled trials included in the meta-analyses of early treatment success in failing/failed synthetic arteriovenous grafts

Study	Year of publication	Country	Outcome measure	Study groups and patients (salvage failures at 3 months/randomised)
Brooks <i>et al.</i> ³⁴	1987	USA	PRP	BA (10/24) vs. S (2/19)
Beathard <i>et al.</i> ³⁵	1993	USA	PRP	BA (6/30) vs. ST (4/28)
Schuman <i>et al.</i> ³⁶	1994	USA	PRP	BA (4/15) vs. S (6/16)
Quinn <i>et al.</i> ³⁷	1995	USA	PRP	BA (19/47) vs. ST (20/40)
Vesely <i>et al.</i> ³⁸	1996	USA	SP	BA (6/10) vs. S (7/10)
Marston <i>et al.</i> ³⁹	1997	USA	PRP	BA (43/59) vs. S (32/56)
Hoffer <i>et al.</i> ²⁸	1997	USA	ASPRP	BA (10/20) vs. ST (7/17)
Dougherty <i>et al.</i> ²⁹	1999	USA	ASPRP	BA (13/39) vs. S (11/41)
Vesely <i>et al.</i> ³⁰	1999	USA	PRP	BA (70/82) vs. S (53/71)
Uflacker <i>et al.</i> ³¹	2004	USA	PRP	BA (25/106) vs. S (19/64)
Vesely <i>et al.</i> ³²	2005	USA	PRP	BA (65/167) vs. CB (67/173)
Haskal <i>et al.</i> ⁴	2010	USA	PRP	BA (47/93) vs. SG (31/97)
Kitrou <i>et al.</i> ³³	2015	Greece	PRP	BA (7/13) vs. DEB (3/13)
Haskal <i>et al.</i> ³	2016	USA	PRP	BA (53/132) vs. SG (48/138)
Vesely <i>et al.</i> ⁵	2016	USA	PRP	BA (78/148) vs. SG (58/145)
Yang <i>et al.</i> ⁶	2018	Taiwan	PRP	BA (17/49) vs. SG (4/49)

BA = balloon angioplasty; S = open surgery; ST = stent; SG = stent graft, DEB = drug eluting balloon; CB = cutting balloon; PRP = primary patency; ASPRP = assisted primary patency; SP = secondary patency.

Table 2. Baseline characteristics of 2011 failing/failed synthetic arteriovenous grafts analysed in this meta-analysis of 16 included randomized controlled trials

Study	Configuration	Graft age	Graft material	Graft status
Brooks <i>et al.</i> ³⁴	All in forearm	NR	Bovine and PTFE	All failing
Beathard <i>et al.</i> ³⁵	NR	19.5 mo*	PTFE	All failing
Schuman <i>et al.</i> ³⁶	NR	611 d*	PTFE	All failed
Quinn <i>et al.</i> ³⁷	NR	533 d*	99% PTFE	67% failed, 33% failing
Vesely <i>et al.</i> ³⁸	All loops in forearm	107 d [†]	PTFE	All failed
Marston <i>et al.</i> ³⁹	Forearm loops 68%, upper arm 32%	8.5 mo*	PTFE	All failed
Hoffer <i>et al.</i> ²⁸	All upper limb loops	365 d*	PTFE	Failing 27, failed 10
Dougherty <i>et al.</i> ²⁹	Forearm 49, upper arm 31	35.3 mo*	PTFE	All failed
Vesely <i>et al.</i> ³⁰	Forearm 75, upper arm 61, thigh 8	NR	NR	All failed
Uflacker <i>et al.</i> ³¹	Forearm 41%, upper arm 50%, thigh 6%	NR	NR	All failed
Vesely <i>et al.</i> ³²	Forearm 48.4%, upper arm 52.6%	24 mo [†]	PTFE	Failing 195, failed 145
Haskal <i>et al.</i> ⁴	Forearm 49, upper arm 140	2.41 y*	NR	All failing
Kitrou <i>et al.</i> ³³	All in upper limb	2.5 y*	NR	All failing
Haskal <i>et al.</i> ³	Forearm 28, upper arm 140	1.8 y*	NR	All failing
Vesely <i>et al.</i> ⁵	Forearm 95, upper arm 198	2.1 y*	NR	Failing 164, failed 129
Yang <i>et al.</i> ⁶	Forearm 29, upper arm 69	39.76 mo*	PTFE	All failing

PTFE, polytetrafluoroethylene; NR = not reported; d = days; mo = months; y = years; failed = thrombosed grafts; failing = dysfunctional grafts with angiographically proved >50% stenosis.

* Mean.

[†] Median.

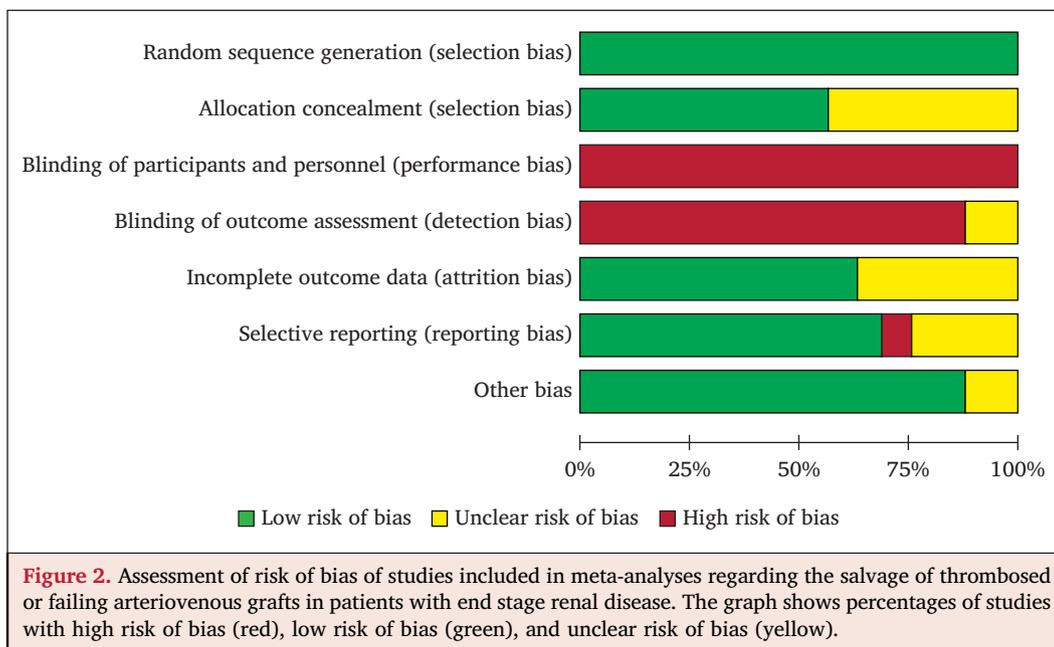
including all trials with a SG arm were of low risk of bias in the remaining domains (Fig. 2 and Appendix I).

Meta-analyses

Pairwise meta-analyses. A pairwise meta-analysis of four studies^{3–6} showed that the risk of failure at three months was significantly lower among patients who underwent SG than those with BA (OR 0.53, 95% CI 0.34–0.83, $I^2 = 53.5%$, p (for heterogeneity) = .09) (Fig. 3). The rest of pairwise meta-analyses did not show any difference between BA and other treatments (seven studies^{29–31,34,36,38,39} for S vs. BA, OR 0.73, 95% CI 0.44–1.20, $I^2 = 37.5%$, p (for heterogeneity) = .14;

three studies^{28,35,37} for ST vs. BA, OR 1.05, 95% CI 0.56–1.97, $I^2 = 0%$, p (for heterogeneity) = .50). Only one study³³ compared DEB with BA (OR 0.26, 95% CI 0.05–1.39) and one study³² also compared CB with BA (OR 0.99, 95% CI 0.64–1.53).

Network meta-analysis. The geometry of the network of treatments that also shows information on risk of bias in the included studies is shown in Fig. 4. The network has a star like shape and BA is the common comparator in all contrasts. Therefore, there is no closed loop of interventions in the network. The five direct comparisons (S vs. BA, ST vs. BA, SG vs. BA, DEB vs. BA, and CB vs. BA) contributed each



equally (20%) to the overall network. Indirect evidence for contrasts between S, ST, SG, DEB, and CB was based on their direct comparisons with BA. For instance, the direct comparisons CB vs. BA and DEB vs. BA contributed each by 50% to the indirect effect estimate for CB vs. DEB.

A league table contains information for pairs of interventions (Table 3). There were no statistically significant differences between treatments regarding the three month failure risk with the exception of SG use, which significantly reduced the risk of primary failure compared with plain BA (OR 0.53, 95% CI 0.34–0.84). Based on SUCRA values (Table 4), DEB and SG were the best treatment options.

The common across contrasts estimate of heterogeneity (tau squared) was 0.30 and the restricted likelihood ratio test for heterogeneity was not significant ($p = .17$).

DISCUSSION

The salvaged procedure of choice for thrombosed or failing AVGs is the most critical question that both patients and clinicians ask. While surgical repair had been the traditional treatment up to the late 1990s, percutaneous endovascular techniques have progressively replaced open repair over the last two decades. Two recent, conventional meta-analyses of RCTs reported that standard angioplasty combined with SG was significantly superior to BA alone in thrombosed or failing prosthetic AVGs.^{24,40} The superiority of SG over plain BA has also been shown in the recent RESCUE trial in treating in stent restenosis too.²⁷ However, other endovascular techniques including cutting balloons, angioplasty combined with STs, and DEBs have never been directly compared with SG use. Previous RCTs indicated that

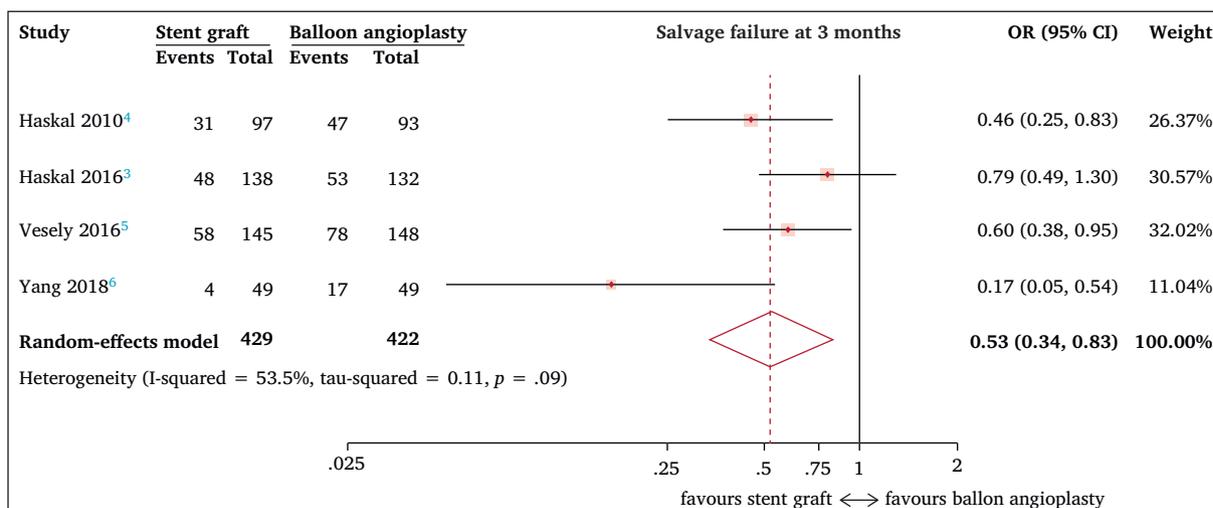


Figure 3. Forest plot of a pairwise meta-analysis of studies that compare the three month risk of failure between stent graft use and balloon angioplasty for salvaging thrombosed or failing arteriovenous grafts in patients with end stage renal disease. CI = confidence interval; OR = odds ratio.

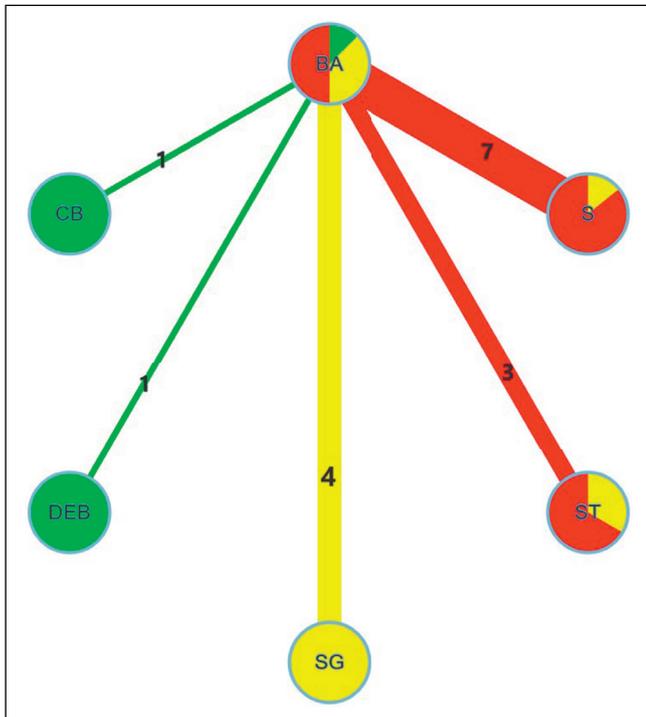


Figure 4. Geometry of the network presenting how each treatment is connected to the others through direct comparisons. The colour of nodes and lines shows the average risk of bias (red suggests high risk of bias, yellow moderate risk, green low risk). The thickness of lines between treatments is weighted according to the number of studies that directly compare them. The figure was produced by the CINeMA software (Confidence in Network Meta-Analysis. Available from cinema.ispm.ch). BA = balloon angioplasty; S = open surgery; ST = stenting; SG = stent graft; DEB = drug eluting balloons; CT = cutting balloons).

bare metal stents or CBs offer no advantage over technically successful angioplasty, while DEB was found to be significantly superior to BA in a single RCT.^{28,32,33} Therefore, a network meta-analysis of RCTs seemed to be a very useful approach for the comparative assessment of all treatments. This NMA of 16 RCTs using data from all sources in published articles including survival curves showed that SG use is indeed better than plain BA in terms of failure risk at three months for thrombosed or failing AVGs in patients with end stage renal disease. Apart from this superiority of

SG over BA, there was no other statistically significant difference between any two treatments in the network.

This NMA also estimated probabilities of each treatment being the best or cumulative probabilities of each treatment being among the best interventions. As shown in Table 4, DEB ranked as the best treatment option followed by SG. An explanation of this finding may be that although SG seems to prevent elastic recoil occurring after plain BA and neo-intimal tissue growth through the stent’s struts, it inevitably produces such growth at the edge of the stent. DEB, unlike SG, is characterised by the “nothing left behind” principle, which means that there is no foreign material left over to irritate the vascular wall.⁴¹ An additional advantage of DEB is that deployment of a SG across the elbow joint is avoided and DEB use does not exclude stenting or open repair at a later stage. In agreement with the findings in grafts, DEB treatment has shown promising results in failing autologous arteriovenous fistulas as well, having performed better than plain BA in three recent RCTs.^{26,42,43} However, probabilities of which treatment is best should be interpreted very cautiously when the network is sparse as in this case. In addition, the evidence for DEB comes from one study of very small sample size, which found an effect estimate of high magnitude that favours DEB.³³ For this reason, less emphasis should be placed on estimated probabilities of best treatments and greater emphasis on treatment effects.⁴⁴

The current work has merits: an extensive and rigorous search was done to identify the totality of eligible studies; trials were analysed on an intention to treat basis; data were obtained from all potential sources within a published article including survival curves; appropriate meta-analytic methods in a frequentist context were used to synthesise the available research evidence; and, finally, the between studies heterogeneity was low. Nevertheless, this NMA is subject to limitations. First, the network geometry is like a star without closed loops. Therefore this NMA was unable to assess consistency between direct and indirect evidence, which increases uncertainty around the findings. Second, trials before 2004 used an open surgery arm, whereas those after 2010 used a SG arm (2010–2018), which might be a source of heterogeneity. Third, the risk of bias in some trials was unclear while most of the trials were very likely to be biased in terms of blinding of participants/personnel and of outcome assessment. However, it is not feasible to blind

Table 3. The off diagonal cells in the league table show the relative treatment effects (odds ratio and 95% confidence intervals) for pairwise comparisons estimated in the network meta-analysis regarding the salvage of thrombosed or failing arteriovenous grafts in patients with end stage renal disease

	Stent	Stentgraft	Open surgery	Drug eluting balloon	Cutting balloon
Balloon angioplasty	1.00 (0.48–2.10)	0.53 (0.34–0.84)	0.73 (0.47–1.15)	0.26 (0.04–1.54)	0.99 (0.48–2.07)
Stent	Not applicable	0.53 (0.23–1.24)	0.73 (0.31–1.73)	0.26 (0.04–1.77)	0.99 (0.35–2.80)
Stentgraft		Not applicable	1.37 (0.73–2.59)	0.48 (0.08–3.05)	1.86 (0.79–4.41)
Open surgery			Not applicable	0.35 (0.06–2.22)	1.35 (0.57–3.20)
Drug eluting balloon				Not applicable	3.86 (0.56–26.68)
Cutting balloon					Not applicable

Odds ratios (ORs) <1 favour (i.e. fewer failures) the treatment in the column. The reciprocals of the odds ratios give effect estimates in the opposite direction. Statistically significant ORs are highlighted in bold.

Table 4. Relative ranking of estimated SUCRA values and of probabilities for being the best for all treatments to salvage thrombosed or failing synthetic arteriovenous grafts in patients with end stage renal disease

Treatment	SUCRA (%)	Probability of being best (%)	Mean rank
Balloon angioplasty	23.2	0.0	4.8
Open surgery	54.6	2.9	3.3
Stent	27.9	1.4	4.6
Stent graft	78.0	17.9	2.1
Drug eluting balloon	87.9	76.5	1.6
Cutting balloon	28.3	1.3	4.6

SUCRA = surface under the cumulative ranking area.

surgeons or researchers in trials regarding surgical and/or endovascular techniques, or to blind assessors as stents or SGs are obvious in duplex ultrasonography.

In conclusion, SG use is better than plain BA to salvage thrombosed or failing AVGs, although the wide confidence interval of the effect estimate downgrades the quality of the available evidence (i.e. confidence in the estimate of effect). The efficacy of DEB certainly deserves further investigation. Future research should include RCTs or even studies with observational design that compare SG use with DEB, especially in selected groups of patients (e.g. in cases in which SGs should be placed across the elbow joint or in thrombosed rather than dysfunctional but still patent grafts where the benefits of SG use are limited).⁵ The use of either SG or DEB, given the healthcare costs of repeat interventions in maintaining failing or failed grafts with plain BA, should also be investigated.

CONFLICT OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2019.06.495>.

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