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SYSTEMATIC REVIEW

Editor's Choice – Network Meta-Analysis of Carotid Endarterectomy Closure Techniques

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WHAT THIS PAPER ADDS

The best method of carotid artery closure following carotid endarterectomy (CEA) is still debated. This systematic review compares the existing methods of closure separating different patch materials in the context of a network meta-analysis. Eversion endarterectomy, as well as patching with bovine pericardium or polytetrafluoroethylene seems to be associated with a lower 30 day combined stroke and death rate and late restenosis following CEA and seems to represent the best choice, compared with other carotid closure techniques.

Objective: There is discordance between reviews comparing eversion endarterectomy (EvE) with conventional carotid endarterectomy (CEA) mostly because under this term various "closure" techniques are included, from direct closure to a wide spectrum of patches with different materials.

Data sources: MEDLINE (via PubMed) and SCOPUS.

Review methods: This was a systematic review of the Medline (via PubMed) and SCOPUS databases for randomised controlled trials (RCTs) comparing different CEA closure techniques. Network meta-analysis (NMA) was performed with a frequentist approach. The primary and the secondary outcome measures were the 30 day combined stroke and death rate and the late restenosis rate, respectively.

Results: Twenty-three RCTs were finally included in the NMA with a total of 4440 patients randomised, representing seven different techniques (primary carotid closure, $n = 753$; EvE, $n = 431$; vein patch closure, $n = 973$; polytetrafluoroethylene [PTFE] patch, $n = 948$; Dacron patch, $n = 828$; bovine pericardium patch, $n = 249$; and polyurethane patch, $n = 258$). NMA showed that EvE had a decreased 30 day combined stroke and death rate *vs.* all other methods of arterial closure, with the exception of PTFE and bovine pericardium patching. Additionally, EvE was associated with the lowest restenosis rate vs. all other methods of arterial closure after CEA. EvE was significantly superior to Dacron patches with regard to late restenosis, with the prediction intervals (PIs) lying completely on the beneficial side (risk ratio 0.06; PI 0.01–0.58) and increasing confidence of this comparison. Rare catastrophic complications of vein patch blow out or synthetic patch infection were reported in 0.2% of the total ($n = 9/4\,400$) and no comparisons were made.

Conclusion: EvE and patching with bovine pericardium or PTFE is associated with a lower incidence in both short term and late undesired outcomes following CEA and seems to represent the best choice compared with other carotid closure techniques. These results may support the vascular surgeon's choice of technique/patch material.

Keywords: Carotid endarterectomy, Carotid stenosis, Eversion endarterectomy, Network meta-analysis, Patch, Systematic review
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INTRODUCTION

Since the first reported carotid artery endarterectomy (CEA) by Eastcott *et al.*[1] at St Mary's Hospital in London, a plethora of studies have investigated various aspects of the procedure in stroke prevention for patients with high grade internal carotid artery stenosis. One of the ongoing issues of debate is the method of arterial "closure" following open CEA.

Several systematic reviews and conventional pairwise meta-analyses have compared the results of primary arteriotomy closure to routine patch closure using various materials, and the outcomes favour patched carotid artery

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closure in reducing the risk of 30 day combined stroke and death and late restenosis. However, there is no agreement on which patch material is the best choice.[2–5] A great variety of patch materials is available for closure of the arteriotomy, including the autologous vein patch, synthetic patches (Dacron, polytetrafluoroethylene [PTFE], and polyurethane), and biological patches (bovine pericardium). An alternative surgical option is eversion CEA. Several systematic reviews and conventional pairwise meta-analyses have compared it with primary closure favouring the former in terms of early and late outcomes.[6,7] Two pairwise meta-analyses comparing eversion with patched CEA have reported contradictory results. However, both studies included various patch materials.[8,9]

The aim of this study was to re-evaluate the role of the various closure techniques and summarise the available evidence of the existing randomised controlled trials (RCTs) in the context of a network meta-analysis.

METHODS

A systematic review was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) reporting instrument (extension statement for network meta-analyses).[10] The analysis included only secondary data from published studies and therefore ethical approval was not required. The study protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (date of submission 21 April 2020 and it is currently under assessment [ID number 181528]). An electronic search for relevant publications was performed using MEDLINE (via PubMed) and Scopus. Medical subject headings, Boolean search operators, and limits in each database were adapted accordingly. A supplementary search for relevant articles was also performed in the Cochrane Database of Systematic Reviews. The following search terms were used: “carotid endarterectomy” AND “patch” AND “eversion endarterectomy” AND “randomized controlled trial*” AND “meta-analysis” [TI, AB, KW]. Two authors (M.K.L. 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 papers were screened for any further studies meeting the inclusion criteria. The final search was carried out on 25 April 2020. A search for relevant articles followed the PICO approach (Participants: patients having indication for carotid endarterectomy; Intervention: open carotid endarterectomy; Comparator: methods of performing open carotid endarterectomy; Outcome [1] 30 day combined stroke and death rate and [2] late restenosis). Two authors performed data extraction using standardised forms for each study (M.K.L. and C.A.). Disagreements and uncertainties at any stage were resolved by discussion.

Eligibility criteria

Studies were considered eligible if (i) they were RCTs, (2) they reported open carotid endarterectomy comparing different techniques of CEA “closure”, and (3) provided data on the 30 day combined stroke and death rate for each group (primary outcome measure) and/or late restenosis (secondary outcome measure). Late restenosis was defined as stenosis $>$50% that appeared $\geq$3 months after CEA and had not been detected on the immediate post-operative duplex examination. The exclusion criterion was the blending of more than one closure technique in one group.

The risk of bias of the included studies was assessed using the revised Cochrane risk of bias tool for randomised trials (RoB 2). This evaluates the risk of bias arising from (1) the randomisation process; (2) deviations from the intended interventions; (3) missing outcome data; (4) measurement of the outcome; and (5) selection of the reported result, and was expressed as either low, of some concern, or high.[11] The risk of bias was assessed at study level. The assessment of risk of bias was done independently by two authors (C.A. and M.K.L.). Discrepancies in data abstraction and evaluation of risk of bias among reviewers were discussed and resolved by consensus. Evaluation of the transitivity assumption by examining the comparability of studies, the absence of systematic differences in baseline clinical characteristics, and potential effect modifiers across comparisons was performed.

Statistical methods

Network meta-analysis (NMA) compares more than two treatment groups. It also makes it possible to compare two treatments, even if they are not compared directly in a single study, as long as they have a common comparator. This is achieved by combining direct and indirect evidence.[12]

The main outcome measure of interest was the 30 day combined stroke and death rate, a dichotomous measure that could be extracted from text, graphs, or life tables. The secondary outcome measure was the late restenosis rate. NMA allows estimation of the relative effectiveness between any pair of treatments. The estimates combining direct and indirect evidence were presented as comparison wise forest plots for all possible pairs of interventions outlining risk ratios (RR) and their 95% confidence intervals (CIs). Differences were considered statistically significant when the 95% CI did not include 1.[12] Prediction intervals were also assessed to enhance the interpretation of findings and provide an estimate of expected results in a future study. The random effects model based on the mvmeta command in STATA (StataCorp, College Station, TX, USA) was chosen for the network meta-analysis.

One of the features of NMA is its ability to rank all competing treatments. It is common to use the “probability of being the best” as a method of finding the best treatment. The surface under the cumulative ranking curve (SUCRA) is used for ranking each treatment’s probability of being better than any other treatment. A SUCRA value of 100% indicates that the treatment is certain to be the most effective, while, conversely, a value of 0% indicates that this treatment is certainly the least effective. Inconsistency in the network, between direct and indirect estimates (the

agreement between direct and indirect evidence) was assessed using the loop specific approach.[13] Publication bias was examined by visual inspection of funnel plot symmetries and Egger's test. The contribution of direct evidence to the whole network was also measured using contribution plots indicating the most influential comparisons. NMA was performed in a frequentist approach with STATA (version 13).

RESULTS

The literature search following removal of duplicates identified 915 articles. The titles and abstracts were screened for relevance and 48 full text articles were read for eligibility (Fig. 1). Of these, 11 articles were excluded as being meta-analyses.[2–9,14–16] Three RCTs were excluded for blending more than one treatment in the same arm,[17–19] another three studies did not include the necessary data to allow calculations,[20–22] and two studies reported the results of the same RCT, which was characterised as a pseudorandomised study.[23,24] Twenty-three RCTs that fulfilled the eligibility criteria were finally included in the NMA detailed in Table 1 (data derived from 29 articles as some authors published early and late results for the same study separately).[25–53] All but two were two armed RCTs, including a total of 4 400 patients randomised to seven different treatments (primary carotid closure, $n = 753$; eversion endarterectomy [EvE], $n = 431$; vein patch, $n = 973$; PTFE patch, $n = 948$; Dacron patch, $n = 828$; bovine pericardium patch, $n = 249$; and polyurethane patch, $n = 258$). The direct treatment comparisons are shown in the network plot (Fig. 2). The main confounders (age, males/females, and symptomatic/asymptomatic patients) were examined in each study and were balanced between groups.

Primary outcome

The results of the network meta-analysis revealed that the 30 day combined stroke and death rate presented statistically significant differences in favour of EvE compared with primary closure, with Dacron patch, vein patch, or polyurethane patch. There was no statistically significant difference between EvE and patch closure with PTFE or bovine pericardium with respect to the 30 day combined stroke and death rate (Fig. 3). Ranking according to 30 day combined stroke and death rate based on SUCRA curves is shown in Table 2. EvE was associated with the highest probability of being the best method of closure (61.1%; SUCRA 92.3%), followed by bovine pericardium (SUCRA 79.3%), and PTFE patch (SUCRA 56.9%). However, the probability of primary closure being the best method of closure was 0%.

Secondary outcome

With respect to late restenosis there were significant differences in favour of EvE compared with patch closure with PTFE, Dacron, bovine pericardium, vein, and with primary closure. PTFE patches caused statistically significantly less late restenosis compared with Dacron patches and primary closure. Additionally, vein patches caused statistically significantly less late restenosis than Dacron patches and primary closure (Fig. 4). Ranking according to late restenosis based on SUCRA curves is shown in Table 3. EvE was associated with the highest probability of being the best method of closure 93.6% (SUCRA 98.7%), followed by PTFE patch (SUCRA 67%) and bovine pericardium patch (SUCRA 61.7%). However, the probability of Dacron patch or primary closure being the best method of closure in respect to restenosis was 0%.

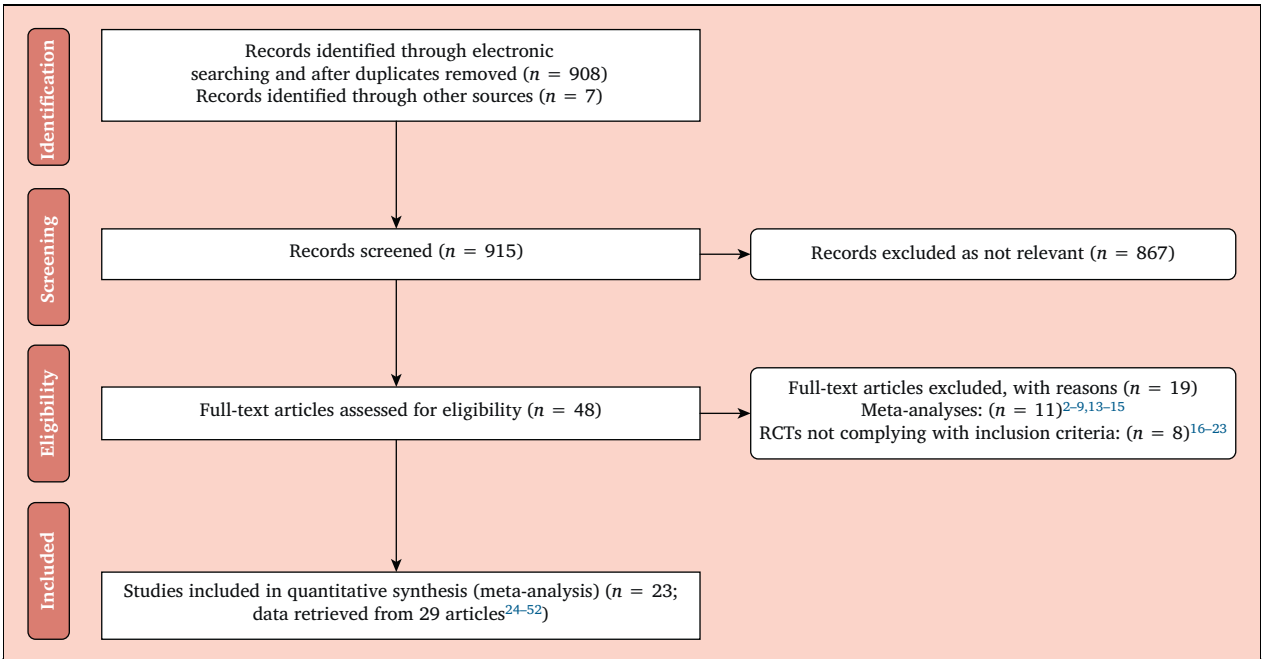

Figure 1. Preferred reporting items for systematic reviews and meta-analysis (PRISMA) flow diagram showing selection of randomised controlled trials (RCT) comparing carotid artery closure techniques following carotid endarterectomy.

Table 1. Characteristics of 23 randomised controlled trials included in the systematic literature review and meta-analysis of different carotid artery closure methods following carotid endarterectomy

First author (year of publication)	Compared treatments	*n*	Asymptomatic − *n*	30 d combined stroke/death − *n*	Late restenosis − *n*	Follow up − mo
Eikelboom (1988),[25] De Letter (1993)[28]	PrC/vein	62/67	11/12	4/3	17/8*	60
Clagett (1989),[26] Myers (1994)[29]	PrC/vein	64/61	14/13	1/0	0/1*	22
Lord (1989)[27]	PrC/vein/PTFE	50/43/47	NR	3/0/0	NR	<1
Vanmaele (1994)[30]	EvE/vein	102/98	NR	4/8	1/2†	12
Katz (1994)[31]	PrC/PTFE	51/49	18/20	2/1	2/0	36
Ricco (1994)[33]	PTFE/vein	66/69	NR	1/1	1/1*	53
Gonzalez Fazarjo (1994)[32]	PTFE/vein	50/45	NR	2/0	2/0	29
Aburahma (1996),[36] Aburahma (1998)[37]	PrC/PTFE/vein	135/134/130	45/46/42	9/3/3	45/3/11*	30
Katz (1996)[34]	Dacron/vein	107/100	50/47	3/1	NR	NR
Albrecht-Fruh (1998)[35]	Dacron/PolUr	52/52	NR	0/3	2/1	12
Ballotta (1999)[38]	EvE/PTFE	169/167	53/56	0/7	0/8*	34
Ballotta (2000)[39]	EvE/PTFE	60/58	30/33	0/2	1/11*	40
Hayes (2001),[40] Naylor (2004)[46]	Dacron/vein	133/134	15/16	3/5	9/2‡	36
O'Hara (2002)[41]	Dacron/vein	97/101	61/50	3/4	3/4†	17
Marien (2002)[42]	Dacron/BovP	44/51	20/24	1/1	NR	12
Aburahma (2002),[43] Aburahma (2003)[44]	PTFE/Dacron	100/100	42/35	0/9	3/30*	25.5
Grego (2003)[45]	PTFE/vein	80/80	26/23	1/1	11/8†	36
Mannheim (2005)[47]	PrC/PolUr	216/206	109/108	2/3	14/4‡	24
Al-Rawi (2006)[48]	PrC/Dacron	175/153	17/14	6/6	NR	12
Aburahma (2007),[49] Aburahma (2008)[50]	PTFE/Dacron	100/100	45/45	2/2	4/12‡	21
Meerwaldt (2008)[51]	Dacron/vein	42/45	0/0	1/4	1/0*	24
Stone (2014)[52]	PTFE/BovP	97/98	65/65	3/1	0/2‡	36
Ignatenko (2019)[53]	EvE§/BovP	100/100	75/73	0/0	4/12*	24

Data are presented as *n* per treatment unless stated otherwise. PrC = primary closure; vein = vein patch; PTFE = polytetrafluoroethylene patch; NR = not reported; Dacron = Dacron patch; EvE = eversion endarterectomy; PolUr = polyurethane patch; BovP = bovine pericardium patch.
* >50%.
† >60%.
‡ >70%.
§ Alternative technique.

The rare catastrophic complications of vein patch blow out or synthetic patch infection were reported in 0.2% of the total ($n = 9/4400$) and no comparisons were made.

Risk of bias

Most trials ($n = 13/23$) were considered to be at low risk of bias. However, in eight trials there was concern of bias in the domain of blinding of assessors. Two trials were judged to be at high risk of bias related to the randomisation process (Fig. 5).

Publication bias and inconsistency

No obvious publication bias was detected in a visual inspection of funnel plot symmetries (Figs. S1 and S2; see Supplementary Material). Furthermore, no significant publication bias was shown with Egger's test in the primary ($p = .71$) and secondary outcomes ($p = .84$). There was agreement between direct and indirect evidence and no significant inconsistency in the NMA results (Figs. S3 and S4; see Supplementary Material).

Regarding the primary outcome, the contribution plot of the network estimated that the direct comparison of vein patch *vs.* Dacron had the largest contribution in the entire network (12%), followed by the comparison of vein *vs.* primary closure (11.6%). Regarding the secondary outcome, the contribution plot of the network estimated that the direct comparison of vein patch *vs.* primary closure had the largest contribution in the entire network (15.9%) followed by the comparison of vein *vs.* PTFE (11.8%) (Figs. S5 and S6; see Supplementary Material).

DISCUSSION

This systematic review and network meta-analysis of the available literature showed that EvE is associated with a decreased risk of early post-operative 30 day combined stroke and death rate *vs.* all other methods of arterial closure with the exception of PTFE and bovine pericardium

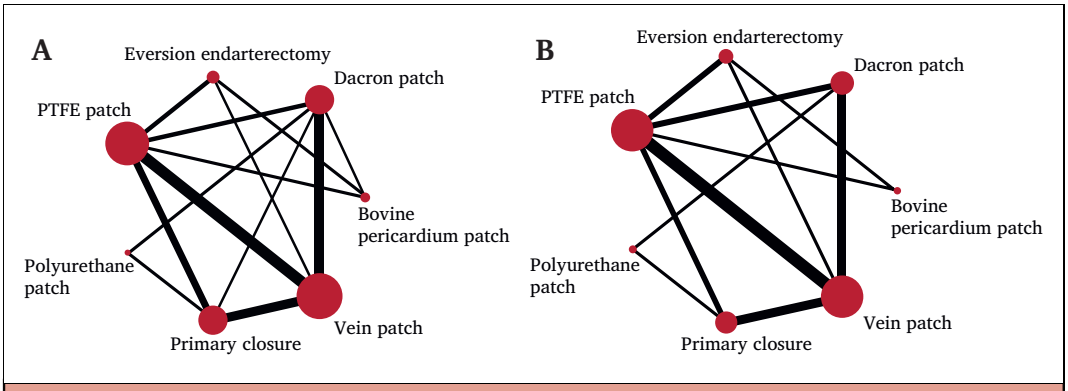

Figure 2. (A) Network geometry plots of the primary outcome (30 day combined stroke/death rate) and (B) secondary outcome (late restenosis) after carotid endarterectomy presenting how each carotid artery closure method is connected to the other closure methods through direct comparisons. The thickness of the lines is proportional to the number of trials comparing the two methods. The size of nodes is proportional to the number of participants randomised to that method. PTFE = polytetrafluoroethylene.

patching. In addition, EvE is statistically significantly superior in terms of late restenosis compared with all other methods of arterial closure after CEA. However, as restenosis was defined as > 50% in most of the included trials, the clinical significance of this finding is questionable, as there is lack of clinical evidence of an asymptomatic restenosis. Also data on the association between recurrent symptoms and restenosis are conflicting.[54]

Primary direct closure has been found to be inferior to patched closure in many trials and observational studies in

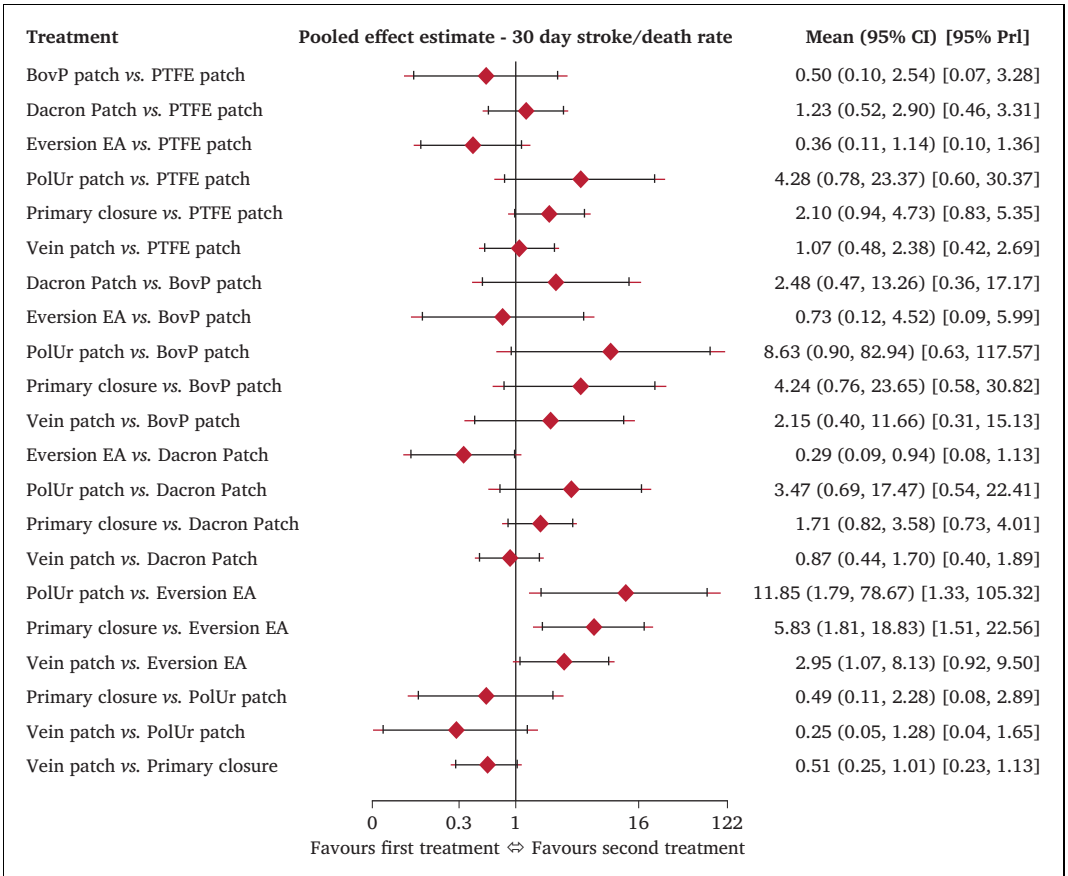

Figure 3. Comparisonwise forest plot of the pooled effect estimates for the primary outcome (30 day combined stroke/death rate) after carotid endarterectomy with different carotid artery closure methods. Risk ratio <1 favours treatment listed first for the comparison. Prediction intervals (PrI) are expressed as red extensions. CI = confidence interval; BovP = bovine pericardium; PTFE = polytetrafluoroethylene; EA = endarterectomy; PolUr = polyurethane patch.

Table 2. Relative ranking of estimated surface under the cumulative ranking curve (SUCRA) values and of probabilities of being the best for all carotid artery closure methods after carotid endarterectomy with respect to the one month combined stroke/death rate based on meta-analysis of randomised controlled trials

Treatment	SUCRA − %	Probability of being best − %	Mean rank
Eversion EA	92.3	61.1	1.5
Bovine pericardium patch	79.3	36.4	2.2
PTFE patch	56.9	1.4	3.6
Vein patch	53.9	0.4	3.8
Dacron patch	44.1	0.3	4.3
Primary closure	17.0	0.0	6.0
Polyurethane patch	6.3	0.3	6.6

EA = endarterectomy; PTFE = polytetrafluoroethylene.

terms of peri-operative stroke rate and late restenosis, and these findings were confirmed in four conventional pairwise meta-analyses.[2–5] While direct closure represents a sub-optimal method of closure, controversy exists regarding the possible benefits of the eversion technique over conventional endarterectomy; four pairwise meta-analyses pooled the results of the existing trials and although the initial impression was eversion technique superiority, sub-group analysis showed that both methods were similar provided the arteriotomy was patched.[6–9] The latter was reflected in the 2018 European Society of Vascular Surgery carotid guidelines.[54] In the present network meta-analysis, there is evidence that these two techniques are equal provided that the patch material is either PTFE or bovine pericardium, and that the use of different patch materials such as autologous vein or Dacron is inferior.

The prediction intervals in a random effects model contain highly probable values for the true treatment effects in future settings.[55] The prediction intervals that lie completely on the beneficial side increase confidence on comparisons of eversion endarterectomy *vs.* polyurethane (Fig. 3) and Dacron patch (Fig. 4). The ESVS guidelines statement that "there is no evidence that patch type influences outcome" was based on a meta-analysis by Ren *et al.*[15] However, in this meta-analysis vein patches were compared with blended synthetic patches and were found to be equally efficient, but in the same meta-analysis when PTFE patches were compared with Dacron patches, statistical significance was observed in favour of PTFE. Similar

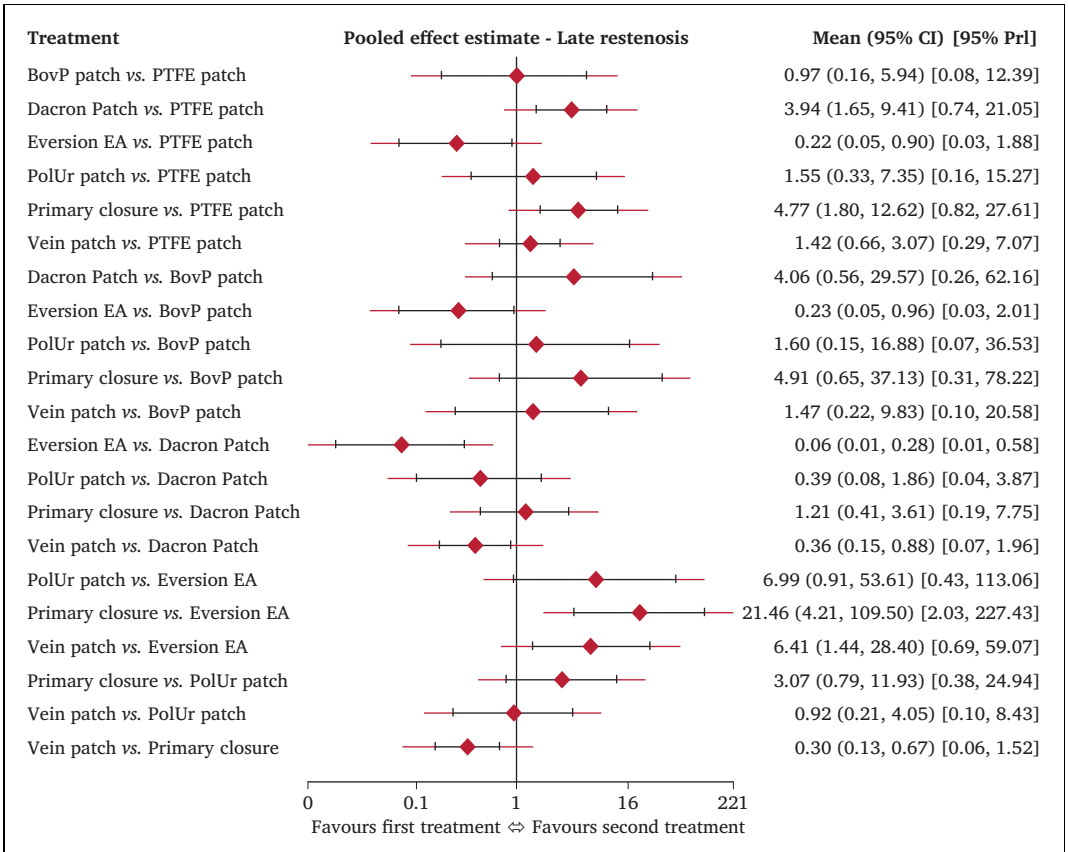

Figure 4. Comparisonwise forest plot of the pooled effect estimates for the secondary outcome (late restenosis) after carotid endarterectomy with different carotid artery closure methods. Risk ratio <1 favours treatment listed first for the comparison. Prediction Intervals (PrI) are expressed as red extensions. CI = confidence interval; BovP = bovine pericardium; PTFE = polytetrafluoroethylene; EA = endarterectomy; PolUr = polyurethane patch.

Table 3. Relative ranking of estimated surface under the cumulative ranking curve (SUCRA) values and of probabilities of being the best for all carotid artery closure methods after carotid endarterectomy with respect to late restenosis rate

Treatment	SUCRA − %	Probability for being best − %	Mean rank
Eversion EA	98.7	93.6	1.1
PTFE patch	67.0	1.3	3.0
Bovine pericardium patch	61.7	2.1	3.3
Vein patch	51.4	0.3	3.9
Polyurethane patch	49.0	2.8	4.1
Dacron patch	14.2	0.0	6.1
Primary closure	8.1	0.0	6.5

EA = endarterectomy; PTFE = polytetrafluoroethylene.

findings in the present study challenge the guideline recommendation.

Three conventional pairwise meta-analyses compared the efficacy of different patch materials in carotid artery closure. Ren *et al.*[15] reported no difference between autologous vein and synthetic patches. However, including PTFE and Dacron patches, they reported that transient ischaemic attack (TIA) and stroke, restenosis >50%, and carotid thrombosis were significantly higher in the Dacron group than in the PTFE group. The mortality rate was similar in both groups, and the haemostasis time in the PTFE group was significantly longer than in the Dacron group. Texakalidis *et al.*[16] also reported no difference between vein and synthetic patches, but again PTFE was blended with Dacron. Additionally, they reported a similar efficacy of bovine pericardium *vs.* other synthetic materials.[16] Rerkasem and Rothwell[4] found, except for pseudo-aneurysms, no differences between vein and synthetic patches, investigating nine early peri-operative and seven late outcomes of interest. In the same meta-analysis, comparison of Dacron with other synthetic patches showed that Dacron was associated with a higher risk of peri-operative combined stroke/TIA and restenosis at 30 days, as well as late stroke and restenosis rate.[4]

The SUCRA scores and the "probability of being best" present readily available results of comparing the efficacy of the different treatments. However, care should be taken in their interpretation. Such rankings do not illustrate the magnitude of the differences between treatments, and only indicate the ranking for only one of several clinically important outcomes. A treatment that is best in one outcome may be the worst in another.[56] Factors such as the shunt insertion policy, type of anaesthesia, and plaque extent may influence the surgeon's choice of closure method. While the results of the present study cannot lead to a recommendation of a specific method of carotid closure, the significant findings may support the indication, that primary direct closure represents the worst choice. Also, the results may encourage future studies to focus on comparing the efficacy of eversion CEA and carotid patching with PTFE or bovine pericardium.

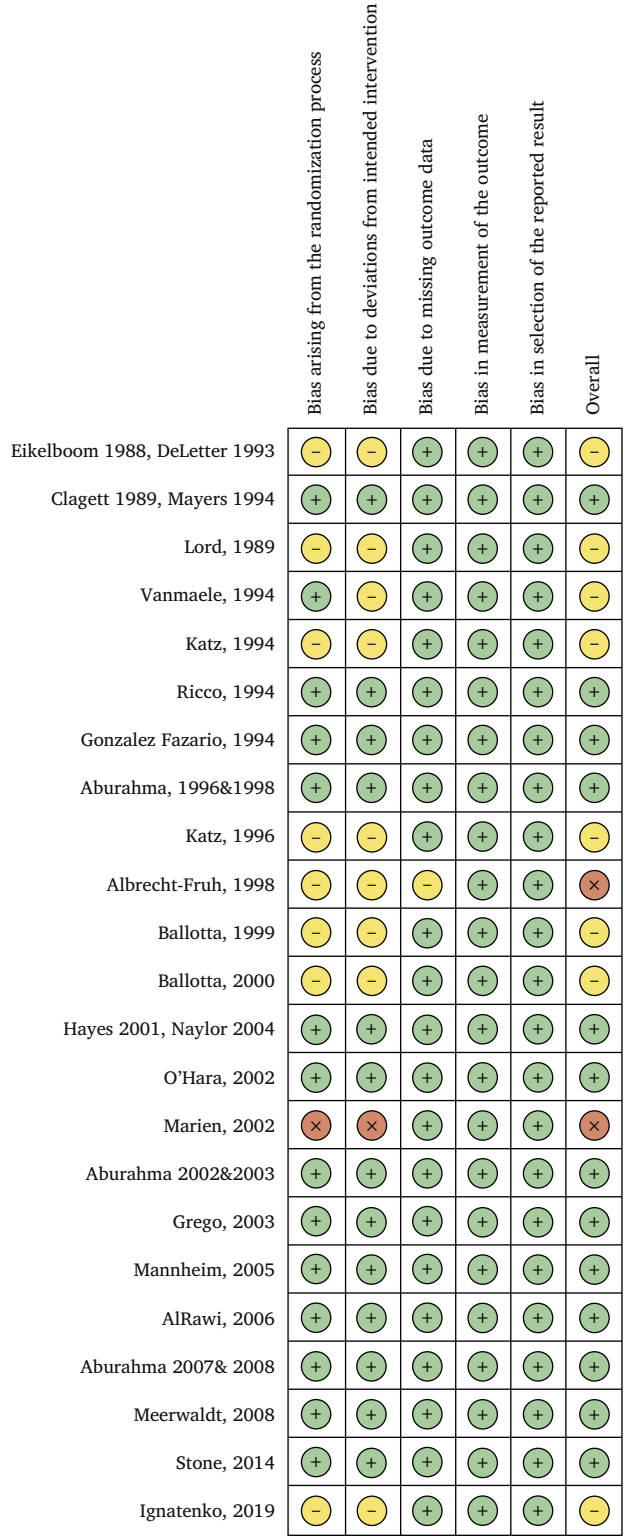

Figure 5. Risk of bias assessment of 23 randomised controlled trials included in the systematic literature review and meta-analysis of different carotid artery closure methods following carotid endarterectomy.

This study has several limitations. Firstly, the low event rate of the investigated clinical outcomes in the total population (any stroke/death rate 2.7% and late restenosis

4.6%) reflect a low risk procedure and do not provide enough power to discriminate between treatments. Another limitation was the pooling of results from RCTs with different designs, surgical techniques, peri-operative care, and follow up protocols. Publication year was a potential modifier, but the investigated outcomes present low event rates and any subanalysis would weaken the power of the analysis. New types of synthetic patches (e.g., Gore-Tex Acuseal) were mixed with older types and with vein patches with different structure (e.g., saphenous vein harvested from groin *vs.* saphenous vein harvested from the ankle or jugular vein) were used. Moreover, there were many different definitions of late restenosis using as thresholds 50%, 60%, or 70%, and a great variety in the length of follow up (Table 1). A further point of concern was the lack of information on whether the stenoses were symptomatic or not, as it was shown that the risk of procedure related stroke and death is different depending on the pre-operative symptom status.[57]

The stroke/death and late restenosis rates were only two of the clinically significant endpoints that should be considered when evaluating the relative efficacy of the compared methods of carotid closure. Haemostasis and intra-operative needle hole bleeding and post-operative hypertension frequently related to EvE because of sinus nerve transection resulting in decreased baroreceptor sensitivity[58] were not studied; however, this NMA was underpowered to investigate rare catastrophic outcomes such as pseudo-aneurysm formation, vein patch blow out, and synthetic patch infections.

In conclusion, EvE and patching with bovine pericardium or PTFE seems to be associated with a lower rate of short term and late outcomes following CEA and seems to represent the best choice, compared with other carotid closure techniques. Future studies should focus on comparing eversion CEA and standard CEA with PTFE or bovine pericardium patches.

CONFLICTS OF INTEREST

None.

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None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2020.10.009.

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Eur J Vasc Endovasc Surg (2021) 61, 190

COUP D'OEIL

A Challenging Proximal Aortic Arch Endovascular Repair

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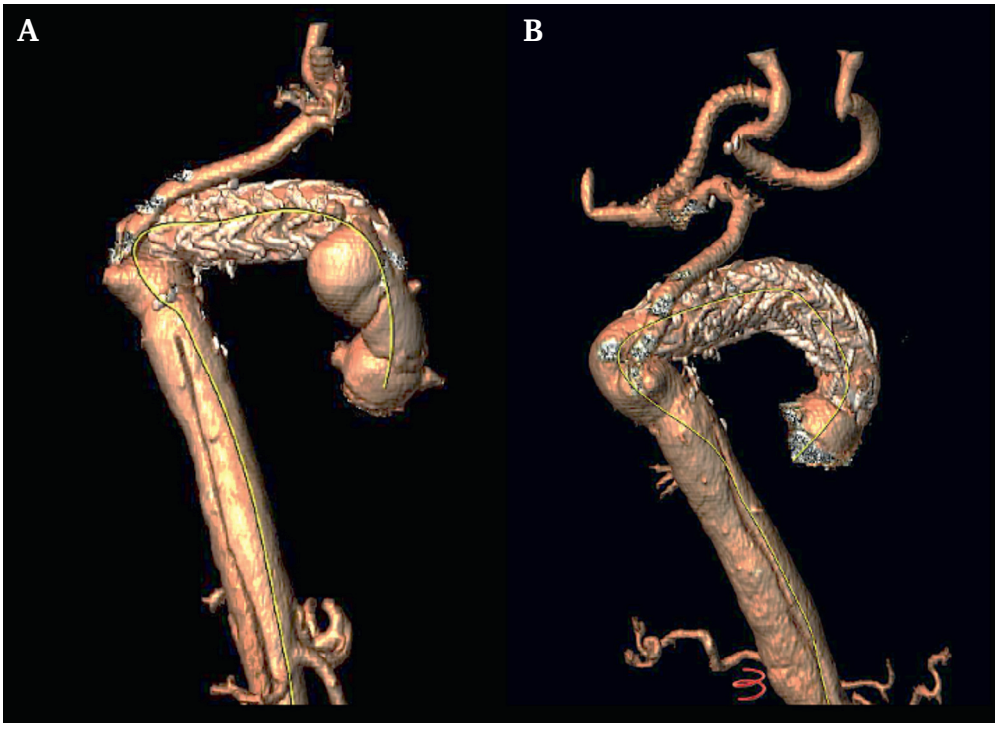

Revision proximal arch thoracic endovascular aneurysm repair (TEVAR) was performed to treat a large, 73 mm pseudoaneurysm in a 74 year old man. (A, B) A through and through guidewire was placed from the right proximal external iliac artery to the left ventricular apex via mini left thoracotomy. A 36 mm Zenith Alpha endograft (Cook Aortic Intervention, Bloomington, IN, USA) was deployed above the level of the coronary sinuses under cardiopulmonary bypass. The patient had a complex history of multiple aortic arch interventions, including a Bentall procedure for type A dissection, hybrid aortic arch TEVAR with retrograde cervical debranching, and a revision Bentall procedure for pseudoaneurysm of coronary sinus and atrial fistula.

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