

A meta-analysis of randomized trials comparing bovine pericardium and other patch materials for carotid endarterectomy



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ABSTRACT

Objective: Patch angioplasty during carotid endarterectomy is commonly used to treat symptomatic and asymptomatic carotid artery stenosis. The objective of the present study was to compare the different patch materials that are currently available (synthetic vs venous vs bovine pericardium) in terms of short- and long-term outcomes.

Methods: This study was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines and eligible randomized control trials were identified through a comprehensive search of PubMed, Scopus, and Cochrane Central published until September 2017. A meta-analysis was conducted with the use of a random effects model. The I^2 statistic was used to assess for heterogeneity. The primary study end point was the incidence of long-term restenosis. Secondary study end points were 30-day stroke, transient ischemic attack (TIA), myocardial infarction, neck wound infection, local hematoma, carotid artery thrombosis, cranial nerve injury, long-term stroke incidence, and death.

Results: Eighteen studies and 3234 patients were included. The risk of 30-day stroke (relative risk [RR], 1.00; 95% confidence interval [CI], 0.45-2.19; $I^2 = 0\%$), TIA (RR, 1.14; 95% CI, 0.41-3.19; $I^2 = 0\%$), myocardial infarction (odds ratio, 0.75; 95% CI, 0.14-3.97; $I^2 = 0\%$), death (RR, 0.53; 95% CI, 0.21-1.34; $I^2 = 0\%$), wound infection (RR, 1.84; 95% CI, 0.43-7.81; $I^2 = 0\%$), carotid artery thrombosis (RR, 1.47; 95% CI, 0.44-4.97; $I^2 = 0\%$), cranial nerve palsy (RR, 1.21; 95% CI, 0.53-2.77; $I^2 = 0\%$), and long-term stroke (RR, 2.33; 95% CI, 0.76-7.10; $I^2 = 0\%$), death (RR, 1.09; 95% CI, 0.65-1.83; $I^2 = 0\%$) and restenosis of greater than 50% (RR, 0.48; 95% CI, 0.19-1.20; $I^2 = 0\%$) were similar between the synthetic vs venous patch groups. Also, no differences in terms of 30-day stroke (RR, 0.31; 95% CI, 0.02-5.16; $I^2 = 63.1\%$), TIA (RR, 0.49; 95% CI, 0.14-1.76; $I^2 = 0\%$), death (RR, 0.74; 95% CI, 0.05-10.51; $I^2 = 31.7\%$), carotid artery thrombosis (RR, 0.13; 95% CI, 0.02-1.07; $I^2 = 0\%$), and long-term restenosis of greater than 70% (RR, 0.15; 95% CI, 0.01-2.29; $I^2 = 70.9\%$) were detected between the synthetic polytetrafluoroethylene and Dacron patch groups. The comparison between the bovine pericardium vs synthetic patch did not yield any statistically significant results in terms of 30-day stroke (RR, 1.44; 95% CI, 0.19-10.79; $I^2 = 12.7\%$), TIA (RR, 1.05; 95% CI, 0.11-10.27; $I^2 = 0\%$), local neck hematoma (RR, 4.01; 95% CI, 0.46-34.85; $I^2 = 0\%$), and death (RR, 4.01; 95% CI, 0.46-34.85; $I^2 = 0\%$).

Conclusions: Closure of the carotid arteriotomy with any of the studied patch materials seems to be similar in terms of short- and long-term end points. However, additional randomized trials with adequate follow-up periods are needed to compare bovine pericardium patches with other patch materials. (*J Vasc Surg* 2018;68:1241-56.)

Keywords: Carotid artery endarterectomy; Synthetic patch; Venous patch; Bovine pericardium patch; PTFE; Dacron

Since the first reported surgical repair of symptomatic carotid artery stenosis in 1954 by Eastcott et al,¹ carotid endarterectomy (CEA) has remained the main treatment

of carotid atherosclerotic disease in both symptomatic and asymptomatic patients.²⁻⁴ Post-CEA restenosis is a well-described adverse event that can lead to multiple carotid interventions and recurrent stroke.⁵⁻⁷

Surgical options comprise conventional CEA and eversion CEA.⁸ Conventional CEA includes a standard longitudinal carotid arteriotomy with or without patch angioplasty (primary closure).^{9,10} In contrast, eversion technique is performed by an oblique transection and eversion of internal carotid artery, followed by reimplantation of the latter into the common carotid artery.¹¹ It remains unclear whether the conventional or eversion approach is superior, owing to the inconsistency of results across the literature.^{10,12} However, previous meta-analyses compared primary closure CEA with patch angioplasty and the outcomes favor the use of a patch to decrease the risk of stroke and restenosis.¹³⁻¹⁵

A variety of patch materials are available for closure of the arteriotomy, including synthetic patches such as expanded polytetrafluoroethylene (PTFE) and Dacron,

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Table I. Important baseline characteristics of patients enrolled in the included studies

Study	Country	Total No. of patients	Synthetic patch group, No.	Venous patch group, No.	Bovine pericardium patch group n	Age mean, years	Males, %
Lord et al (1989) ²¹	Australia	123	47	43	—	47	44
Gonzalez-Fajard (1994) ²²	Spain	84	50	45	—	70	88
Ricco et al (1994) ²³	France	135	66	69	—	63	80
Katz et al (1996) ²⁴	USA	190	107	100	—	71	49
AbuRahma et al (1996) ²⁵	USA	264	134	130	—	68	51
AbuRahma et al (1998) ²⁶	USA	264	134	130	—	68	51
Hayes et al (2001) ²⁷	UK	273	136	137	—	70	67
O'Hara et al (2002) ²⁸	USA	195	94	101	—	69	74
Marien et al (2002) ²⁹	USA	95	44	—	51	66	64
Grego et al (2003) ³⁰	Italy	160	80	80	—	70	62
Naylor et al (2004) ³¹	UK	273	136	137	—	70	67
Meerwaldt et al (2008) ³²	Netherlands	87	42	45	—	66	79
Aburahma et al (2002) ³³	USA	180	PTFE (100) vs Dacron (100)	100	—	75	59
Aburahma et al (2003) ³⁴	USA	180	PTFE (100) vs Dacron (100)	—	—	75	59
Aburahma et al (2007) ³⁵	USA	200	PTFE (100) vs Dacron (100)	—	—	68	49
Aburahma et al (2008) ³⁶	USA	200	PTFE (100) vs Dacron (100)	—	—	68	49
Aburahma et al (2009) ³⁷	USA	200	PTFE (100) vs Dacron (100)	—	—	68	49
Stone et al (2014) ³⁸	USA	195	97	—	98	67	55

BP, Bovine pericardium; *CAD*, coronary artery disease; *HTN*, hypertension; *NR*, not reported; *PTFE*, polytetrafluoroethylene; *SP*, synthetic patch; *Sx*, symptomatic; *VP*, venous patch.

autologous venous tissue patches (mostly saphenous and external jugular vein) and biomaterial patches, the most popular being bovine pericardial patch.¹⁶ Reaching conclusions for the optimal patch material is thus very important not only to improve periprocedural outcomes, but also to decrease the long-term restenosis rate and recurrent stroke rate in patients with carotid artery stenosis undergoing patch angioplasty. Our aim in this study was to systematically review the literature for randomized controlled trials (RCTs) comparing different patch material use during CEA with regard to their short- and long-term outcomes.

METHODS

This review protocol has been registered in the PROSPERO International Prospective Register of systematic reviews (http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017078299). This systematic review and meta-analysis was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines.¹⁷

Search strategy and inclusion criteria. Systematic literature searches were conducted in PubMed, Scopus, and Cochrane Central. The search strategy used for PubMed was the following: carotid AND (endarterectomy OR CEA) AND ("primary closure" OR eversion OR patch OR interposition) AND (randomized OR RCT OR "randomized control trial" OR randomly). The search was conducted by two independent investigators (PT, SG). Disagreements were resolved by a third investigator (NC). The references of the included studies were also manually reviewed to identify further eligible articles.

A study was considered eligible for this meta-analysis if it fulfilled all of the following inclusion criteria: (1) RCTs comparing different patch types, (2) studies that reported quantitative data on clinical outcomes of interest, and (3) studies published in English up to September 2017. When duplicates were identified, the most recent study was included unless the earliest version reported more relevant outcomes.

Data extraction and study end points. Two reviewers, blind to each other (PT, SG), independently extracted the relevant data from the eligible studies. All disagreements

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