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Review Article

Selection criteria for patch angioplasty material in carotid endarterectomy

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ABSTRACT

Background: Carotid endarterectomy (CEA) with patch angioplasty has been favored due to its lower reoccurrence of restenosis compared to primary CEA. There are multiple types of patch angioplasty material available. However, selection of patch material is based on uncertain criteria. The aim of this study is to determine the ideal criteria for selecting the best patch material for CEA.

Methods: We conducted a comprehensive literature search for studies that describe the ideal criteria for selecting patch material for CEA. We compiled all of the criteria mentioned into one table and selecting the criteria which were most frequently mentioned with a simple scoring system.

Results: A total of 65 studies out of 784 studies were assessed for its full-text eligibility. Thus, we found 23 studies that were eligible for analysis. There are 22 ideal criteria that were mentioned in the analyzed studies. We grouped these criteria into physical characteristics, safety, contribution to hemodynamic, contribution in tissue healing, economic aspect, and ability to prevent postsurgical complication. We proposed 10 ideal criteria for guiding vascular surgeon in selecting the best patch angioplasty material.

Conclusion: To this day, no material has been discovered which meets all ten criteria. This study's proposed ideal criteria serve as the foundation for the creation of the best patch angioplasty material.

Keywords: Carotid endarterectomy, Ideal criteria, Material, Patch angioplasty

INTRODUCTION

Carotid endarterectomy (CEA) remains a mainstay treatment for carotid stenosis since it was first conducted in 1954 by Eastcott *et al.*[14] The indication of this procedure is for symptomatic patient with stenosis >50% and asymptomatic patients with stenosis >60%.[36] However, primary CEA is often associated with restenosis, which can lead to multiple intervention and recurrent stroke.[9,26] Other techniques that are widely conducted are patch angioplasty CEA. Several systematic reviews have shown that patch angioplasty can lower perioperative morbidity, long-term risk of stroke, and restenosis compared to the primary CEA.[10,20,44]

There are several materials that can be used for patch angioplasty, those are autologous vein, prosthetic patches (polytetrafluoroethylene [PTFE], Dacron, polyurethane, and polyester), and

biologic patches (bovine pericardium and decellularized extracellular matrix). However, the outcome of different patch materials seemed to be similar in terms of short- and long-term results.[49]

Vascular surgeons have not been able to identify the specific and clear guidance in choosing materials for patch angioplasty. This systematic review aimed to find the ideal criteria for patch angioplasty in CEA and whether the materials that were studied have fulfilled the ideal criteria or not.

MATERIALS AND METHODS

Literature search

The search strategy was in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidance. We performed a literature search in PubMed and SCOPUS in June 8, 2021. The keywords that were used are carotid AND Endarterectomy AND Patch. The detailed search terms can be seen in the Supplementary Table 1. The search was conducted by two independent investigators. Any disagreement will be discussed by the two investigators.

Eligibility criteria

The articles included in this research met the following criteria: (1) experimental procedure in human carotid artery, (2) mentioned the ideal criteria for selecting patch angioplasty material, (3) revealed the source of the patch material, (4) parameter used to evaluate complications, (5) examined a single type of material during study, and (6) the full text is available in English. Any duplicated unavailable full texts, review papers, case reports, case series, or abstract-only papers are not included in our review.

Data extraction

Two reviewers blind to each other independently extracted the relevant data from the included studies. Any disagreements will be resolved through discussion among the two reviewers. The data that were obtained from the full-text review are author, year of publication, number of subjects, and material that were used, ideal criteria for patch angioplasty material, time of follow-up, complications observed, and fulfillment of the ideal criteria.

RESULTS

The search engine PubMed and SCOPUS provide a total of 784 articles. Duplications were found using EndNote X9, excluding 65 articles. Screening of title and abstract by our reviewers excluded 654 articles. Additional 42 full-text articles were excluded due to its inability to fulfill the eligibility criteria; thus, 23 articles were included in our study [Figure 1].

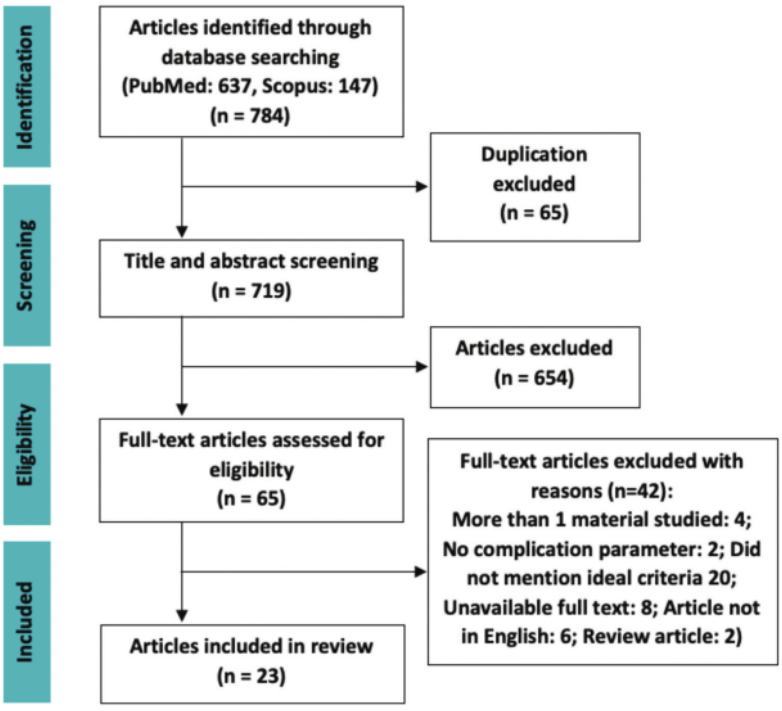

Figure 1: PRISMA flow diagram for the selection of studies in systematic review.

Table 1: Ideal criteria of patch material in the included studies.

Criteria	McCready *et al.* (2021)[35]	McCready *et al.* (2005)[34]	Ladowski and Ladowski (2011)[28]	Mannheim *et al.* (2005)[31]	AbuRahma *et al.* (2005)[2]	AbuRahma *et al.* (2001)[1]	Archie (1987)[4]	Archie (1986)[3]	Biasi *et al.* (2002)[8]	Biasi *et al.* (1996)[7]	Danikas *et al.* (2001)[12]	Ricco *et al.* (2000)[46]	Meyer and Windschitl (1998)[37]	Eikelboom *et al.* (1998)[16]	Plestis *et al.* (1996)[42]	Perler *et al.* (1995)[41]	Rhodes. (1995)[45]	Myers *et al.* (1994)[39]	Katz *et al.* (1994)[23]	De Letter *et al.* (1994)[13]	LeGrand and Linehan (1990)[38]	Clagett *et al.* (1989)[11]	Hans (1987)[18]	Scoring
Physical characteristic																								
Easy to handle			v	v					v	v		v		v	v			v		v	v			10
Resist suture bleeding						v			v															2
Easy to close										v				v										2
Strong/low risk of rupture			v	v	v	v							v	v			v	v	v			v		10
Appearance on ultrasound			v																	v				2
Enough coverage																v								1
Safety																								
Resistant to infection	v	v	v	v									v	v		v		v	v	v	v			11
No immunologic reaction			v						v	v														3
Less bleeding				v	v										v		v		v					5
Hemocompatible/low rate thrombosis		v		v		v		v		v	v	v		v	v	v		v	v	v	v	v		15
Contribution to hemodynamic																								
Mechanical resistance	v		v										v				v							4
Supports blood flow/low turbulence							v										v					v		3
Provides early patency		v									v							v						3
Contribution in tissue healing																								
Biodegradable	v																							1
Prevent intimal hyperplasia				v										v		v			v					4
Provides endothelialized surface	v						v		v	v						v		v				v		7
Economic aspect																								
Readily available		v	v	v	v	v											v				v	v		9
Low cost			v												v									2
Prevent postsurgical complication																								
Prevent restenosis			v	v	v			v		v	v		v	v				v	v	v				v	12
Prevent pseudoaneurysm		v		v	v									v			v		v	v		v		9
Low neurologic complication				v	v									v				v	v	v		v	v	8
Prevent cervical hematoma		v	v												v									3

Most referred criteria if mentioned in≥5 studies based on the literature[33]

The simple scoring system conducted in our study was derived from a study by Bolly *et al.*, which able to determine the ideal criteria for duraplasty material.[33] The method proposed in his review study was deemed applicable for our study.

We compiled all of the ideal criteria and grouped those criteria into physical characteristics, safety, contribution to hemodynamic, contribution in tissue healing, economic aspect, and ability to prevent postsurgical complication. All of the findings of ideal criteria were listed into a table, and the dominant ideal criteria should have been mentioned in at least five papers. There are 10 criteria that are considered as the most dominant and the most ideal ones (mentioned ≥5 times), those are easy to handle, durable/low risk of rupture, resistant to infection, less bleeding, hemocompatible, provide endothelialized surface, readily available, prevent restenosis, prevent pseudoaneurysm, and low neurologic complication [Table 1]. The safety group becomes the most dominant criteria; due to the high possibility of complication, if the safety criteria cannot be fulfilled. Physical characteristics are also largely considered since it will affect the surgical technique and time. We also present the characteristics of the included studies [Table 2].

DISCUSSION

CEA for carotid artery stenosis is indicated by European Society of Cardiology for symptomatic patients with stenosis >50%, while asymptomatic patients indicated to be intervened when stenosis >60% and had high long-term risk of stroke.[19] Since the restenosis rate of primary CEA has been quite substantial, the surgical technique of CEA has been debated for many years, whether to perform a primary closure CEA or patch angioplasty CEA.[5,6] A systematic review conducted by Huizing *et al.*, reviewed a total of 12,696 patients who underwent CEAs, and found that perioperative stroke rate and restenosis rate were lower in patch angioplasty CEA.[21] However, the quality is moderate and data on long-term stroke remain unclear. The standard of care to conduct patch angioplasty or primary closure CEA remains unclear, and the ideal materials that may provide significant advantage are still being researched.[32,35,38] Several materials that are commonly used for patch angioplasty CEA include autologous vein, synthetic materials (expanded polytetrafluoroethylene and Dacron), and biologic patches (bovine pericardium and decellularized extracellular matrix).[35,38] Nevertheless, evidence supporting the superiority of one material is lacking, and ongoing research aimed at discovering the "holy grail" material is still ongoing.[49] There is no specific guidance on the ideal criteria that needed to be fulfilled by a selected material. The ideal criteria that are being proposed in various studies usually varied and based on an institution experience. Therefore, we conducted a study determining the most dominant ideal criteria by conducting a systematic review of the literature.

Our review found that the main ideal criteria are as follows: easy to handle, durable/low risk of rupture, resistant to infection, less bleeding, hemocompatible, provides endothelialization, readily available, prevent restenosis, prevent pseudoaneurysm, and provide low neurologic complication. At present, there is no material that is able to fulfill all of those ideal criteria.

Historically, autologous veins are being favored for conducting patch angioplasty CEA, since it provides endothelialized surface, similar to the surrounding arterial tissue, easy handling, and low risk of infection. However, its apparent disadvantages, such as the extended operation duration, the probability of wound complications at the harvest site, and the likelihood of rupture and pseudoaneurysm, cannot be overlooked.[30] Thus, synthetic patches (PTFE and Dacron) were being developed to overcome the autologous vein shortcomings. These synthetic patches had obvious strengths such as readily available, durable against aneurysmal formation and patch rupture, and less surgical time since the autologous vein is preserved.[43] Yet, these synthetic patches are not without its shortcomings. Both Dacron and PTFE have an increased risk of infection compared to autologous vein, suture bleeding with PTFE use, and prolonged hemostasis time. Efforts have been made to reduce the bleeding risks with these synthetic patches, such as the use of collagen-impregnated knitted Dacron and hemostatic modified PTFE.[10] The results have been promising; however, the superiority of the material still cannot be achieved based on the recent meta-analysis of randomized controlled trials.[49] Biomaterial patches, such as bovine pericardium, are quite popular because they are widely accessible, durable, biocompatible, and allow for immediate ultrasound usage following implantation. This material is widely used in cardiovascular surgery since it has smooth non thrombogenic surface and excellent hemocompatibility.[15] Unfortunately, reports on possibility of bovine spongiform encephalopathy have decreased its popularity.[38] Nevertheless, its biocompatible characteristic has been proven by Edenfield *et al.* who conducted an analysis of 70.987 CEA procedure within Vascular Quality Initiative database, where bovine pericardium had lower rates of postoperative events and 1-year restenosis compared to other patch materials.[15] Another biomaterial that has been used clinically is biologic extracellular matrix from porcine small intestinal submucosa. This patch material is biodegradable, in a sense that the host tissue will replace the patch material overtime. Yet, the outcome of this patch has only been reported by a single-center study; thus, further research examining this particular material is needed.[35]

Table 2: Characteristics of the included studies.

No.	Study	Material	Group	Subjects	Length of follow-up	Complications	Fulfill the ideal criteria
1	McCready *et al.* (2021)[35]	CorMatrix (Porcine SIS)	Biomaterial	275	72 months (range: 49–85 months)	Nine had postoperative stroke, 13 resurgery due to restenosis, one resurgery due to bleeding, one pseudoaneurysm	Resistant to infection, durable, low risk of thrombosis
2	McCready *et al.* (2005)[34]	CorMatrix (Porcine SIS)	Biomaterial	76	4–6 weeks, 6 months, yearly	2 had postoperative stroke, 1 cervical hematoma, three resurgery due to restenosis, seven pseudoaneurysm	Durable, biodegradable, provides patency, resistant to infection, resist suture bleeding, easy to handle
3	Ladowski and Ladowski (2011)[25]	Bovine pericardium	Biomaterial	775	19.2±16.8 months	24 arteries had significant stenosis, two had critical stenosis; four patients had cervical hematoma, five patients had perioperative stroke	Readily available, resistant to infection, low cost, less bleeding
4	Mannheim *et al.* (2005)[31]	Polyester urethane	Synthetic	206	2.5–5 years (median: 2 years)	Five had TIA, three had stroke, five had postoperative bleeding, one had infection, five had cranial nerve damage, 13 had recurrent stenosis	Low restenosis rate
5	AbuRahma *et al.* (2005)[2]	Modified polytetrafluoroethylene (PTFE)	Synthetic	187	21 months (range: 1–48 months)	Three had stroke, seven had TIA, two had cervical hematomas, nine had cranial nerve injury, one had infections, six had>70% restenosis (two had resurgery)	Readily available, prevent pseudoaneurysm, low rate of thrombosis, low rate of neurologic complication, low rate of restenosis
6	AbuRahma *et al.* (2001)[1]	Collagen-impregnated Dacron (Hemashield)	Synthetic	144	12 months	TIA+Stroke in 12% of patients, recurrent stenosis>50% in 21%s	No
7	Archie (1987)[4]	Saphenous vein	Autologous	50 CEA	6–18 months	No complications reported	Provide endothelialized surface, low turbulence, prevent restenosis, and early post thrombosis
8	Archie (1986)[3]	Vein patch	Autologous	100	1 year	No complications reported	Nonthrombogenic, easy to handle, resist infection
9	Biasi *et al.* (2002)[8]	Bovine pericardium	Biomaterial	323	108 months	Five had major perioperative cerebrovascular incident, three deaths, four had resurgery	Resistant to infection, less bleeding, low rate of restenosis, easy to handle
10	Biasi *et al.* (1996)[7]	Bovine pericardium	Biomaterial	49	12–30 months	Three have cranial nerve palsies, one had infection, two had significant restenosis	Easy to handle, hemocompatible, no immunologic reaction

(*Contd...*)

Table 2: (*Continued*).

No.	Study	Material	Group	Subjects	Length of follow-up	Complications	Fulfill the ideal criteria
11	Danikas *et al.* (2001)[12]	Double-layer saphenous vein	Autologous	168	3–74 months	Two had early postoperative neurologic deficit	Durable, prevent pseudoaneurysm, great mechanical resistance
12	Ricco *et al.* (2000)[46]	Polyester collagen	Synthetic	207	726 days (median)	Three postoperative deaths, one had cervical hematoma complicated with stroke, four had postoperative occlusion, restenosis rate 5% at 2 years and 12.1% at 3 years	low turbulence, hemocompatible, prevent intimal hyperplasia, easy handling, less bleeding, durable, provides early patency
13	Meyer and Windschitl (1998)[37]	Collagen-impregnated Dacron (Hemashield)	Synthetic	146	1–3 years	Two had stroke, two had RIND, two had cerebral hemorrhage, two had recurrent stenosis, one had graft infection	Prevent restenosis, durable
14	Eikelboom *et al.* (1998)[16]	saphenous vein	Autologous	67	20 months	Two had>50% restenosis	Low restenosis rate
15	Plestis *et al.* (1996)[42]	Vein patch	Homologous	837	1–132 months (mean 61 months)	Eight perioperative deaths, 27 had cervical hematomas, two had cranial nerve injury. Long term: neurologic complication in 20 patients, recurrent stenosis in 24 arteries	Low cost, hemocompatible, ready availability
16	Perler *et al.* (1995)[41]	Dacron	Synthetic	115	1–49 months (mean 16.8 months)	One death, two perioperative stroke, residual stenosis 4.5%, and recurrent stenoses 4.8%. Perioperative complications: 9.2% cardiac, neck hematoma 4.2%, and cranial nerve injury 4.2%	Low restenosis rate and pseudoaneurysm
17	Rhodes (1995)[45]	Expanded polytetrafluoroethylene (PTFE)	Synthetic	753	41.4 months (0–197 months)	Six deaths, seven had nonfatal strokes, and 19 had hemorrhages. Recurrent stenosis in 84 (8.9%), 28 (3.7%) needed surgery. Two postoperative infections	Readily available, low rate of restenosis, prevent pseudoaneurysm, great mechanical resistance
18	Myers *et al.* (1994)[39]	Saphenous vein	Autologous	99	54.8–66.2 months	One had TIA, one had major strike, four had cranial nerve dysfunction, and one had resurgery. Long term: 11 had restenosis, eight had stroke, one had resurgery	No
19	Katz *et al.* (1994)[23]	Expanded polytetrafluoroethylene (PTFE)	Synthetic	43	29.2 months	One had major stroke, one had TIA , one had infection	Low restenosis rate and neurologic deficit

(*Contd...*)

Table 2: (*Continued*).

No.	Study	Material	Group	Subjects	Length of follow-up	Complications	Fulfill the ideal criteria
20	De Letter *et al.* (1994)[13]	saphenous vein	Autologous	67	5 years (range: 1–96 months)	Two deaths, one patch rupture	Low neurologic deficit
21	LeGrand and Linehan. (1990)[28]	Expanded polytetrafluoroethylene (PTFE)	Synthetic	175	N/A	One had stroke, one had asymptomatic occlusion, two had high-grade restenosis	Readily available, durable, prevent pseudoaneurysm
22	Clagett *et al.* (1989)[11]	Saphenous vein	Autologous	92	18–26 months	One had TIA, one had major stroke, and four had cranial nerve dysfunction. Long term: eight had restenosis, two had TIA, two had stroke	Low restenosis rate in women
23	Hans. (1987)[18]	Vein patch	Autologous	78	36 months (range: 12–60 months)	1.2% had transient neurologic deficit, six deaths, three had restenosis	Provide early patency, low rate of neurologic deficit, hemocompatible

In our review, the most frequently selected ideal criteria were hemocompatibility, since a thrombogenic substance might induce postoperative stroke, resulting in severe morbidity for the patients. After implantation of vascular patch, plasma protein will be absorbed immediately; they contain binding sites for integrin receptors, which can be found on platelets and many cells. Platelets may become activated as a result of adhesion to these receptors.[47] An endothelialized surface will reduce the activation of platelets significantly, since endothelialized surface can act as physiological layer that can adapt to hemodynamic stresses of the carotid artery.[35] At present, available synthetic material cannot provide this characteristic; thus, biomaterial patches that allow host tissue endothelialization are being developed.[27]

Resistance to infection is also important in providing a safe patch angioplasty CEA. Braided sutures in the synthetic patches can trap bacteria in their interstices, thus providing nidus of infection. Synthetic patches such as PTFE have been modified using monofilament sutures to eliminate this risk. However, the number of infections in synthetic patches is still considerably higher than other materials.[24,38,48] Biomaterial patches and autologous vein have been extensively reported to have a low risk of infection; consequently, the creation of materials with this capability is required.[38] We provide a simplified history timeline of the development of patch angioplasty material [Figure 2]. Note that not every single material was included in this simplified timeline, for example, the various autologous vein (external jugular, facial vein, or homologous vein patch), modified synthetic material (polyurethane and polyester), and other biologic patches that were only tested in animal studies.[38] This simplified timeline was made to help readers to understand the dynamic changes of the ideal criteria. The finding of new material will create new ideal criteria, and the advancement in the vascular studies will demand a more reliable patch angioplasty material in the future.

Limitations

Our study focused on patch material as a main contributor for a successful CEA procedure. However, we cannot disregard other factors that may contribute to post-CEA complications. One of our proposed ideal criteria and the main goal of any carotid artery stenosis intervention are prevention of restenosis. Although patch material is knowingly affected restenosis rate, arterial intervention itself can promote restenosis.[29] Other factors in patch angioplasty CEA that may increase restenosis rate are surgical technique, patch width, location of arteriotomy, and carotid artery biomechanics.[5,22]

Future directions

Historically, the characteristics of patch angioplasty which were desired are those with low risk of pseudoaneurysm, prevent rupture, and readily available, since autologous vein cannot provide these characteristics. Synthetic materials and biomaterials are being developed to solve these problems. However, with the use of these foreign materials, several problems ensued. Synthetic materials such as PTFE and Dacron are still at risk for infection, can be thrombogenic, and had prolonged hemostasis time.[43] Biomaterials such as bovine pericardium and biologic extracellular matrix from porcine are desired to overcome the shortcomings of the synthetic materials. Unfortunately, recent systematic review

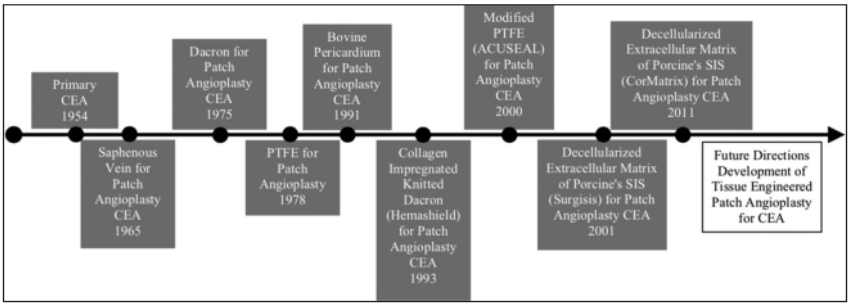

Figure 2: Simplified history timeline of patch angioplasty material's development for carotid endarterectomy.

and meta-analysis still cannot provide evidence the clinically available biomaterials are superior than the synthetic or the autologous ones.[49]

Development of tissue-engineered patch angioplasty is hoped to provide a patch material that can fulfill all of the proposed ideal criteria. The advantage of tissue engineered patch angioplasty is providing a material that integrates with host tissue and has characteristic like a native vessel; thus, the desired ideal criteria can be achieved. One of the most promising tissue-engineered vascular tissues is by nanofiber composites, which combine natural and synthetic polymers.[40] Biomaterials such as collagen, gelatin, chitosan, and elastin have great biocompatibility to the native vessel. However, these materials had poor mechanical properties.[17] Addition of synthetic degradable polymer can overcome the drawbacks of biomaterial, since it can be synthesized flexibly and had excellent mechanical properties. *In vitro* investigations have previously demonstrated the superiority of these materials. Some *in vivo* experiments have also been conducted with these materials, demonstrating the tremendous potential of nanofiber composites.[27,40] No single composites have been approved for clinical use yet, thus further research developing these materials are essential for the creation of the ideal patch material.

CONCLUSION

This review provided 10 ideal criteria that can be used to help surgeons to choose a material for patch angioplasty CEA. Up until this day, material than possesses all of the 10 criteria has not yet been found. The ideal criteria in this review serve as foundation in the development of the ideal patch angioplasty material for CEA procedure.

Disclosures

The authors have no relevant financial or nonfinancial interest to disclose.

Declaration of patient consent

Patients' consent not required as there are no patients' in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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SUPPLEMENTARY

Supplementary Table 1: Search Terms for Database Search

No.	Databases	Search terms	Total
1	PubMed	"Carotid endarterectomy" (Title/Abstract) and ("patch" [Title/Abstract] or "graft" [Title/Abstract])	637
2	Scopus	TITLE-ABS-KEY ([carotid] and [endarterectomy] and [patch or graft] AND "clinical trial")	147

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