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Patch angioplasty during carotid endarterectomy using different materials has similar clinical outcomes

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ABSTRACT

Objective: Patch angioplasty during carotid endarterectomy (CEA) is commonly used to treat carotid artery stenosis. However, the choice of which patch to use remains a matter of debate. Autologous venous material has disadvantages such as wound-related problems at the harvest site and a prolonged intervention time. These limitations can be bypassed when synthetic or biological patches are used. Both materials have been associated with divergent advantages and disadvantages. Therefore, the aim of our study was to compare the long-term follow-up outcomes in patients who underwent CEA and closure with either a bovine pericardial patch (BPP) or polyester patch.

Methods: A retrospective cohort study was conducted including all patients who underwent primary CEA and closure with a BPP or a polyester patch between January 2010 and December 2020 at our tertiary referral center. In 2015, the BPP was introduced as an alternative for polyester. The primary outcome was the occurrence of transient ischemic attack (TIA) or cerebrovascular accident (CVA) during follow-up and secondary outcomes included restenosis, reintervention, all-cause mortality, and patch infection. Cox proportional hazard models were used and hazard ratios with 95% confidence intervals were used to predict these outcomes.

Results: We included 417 CEA patients; 254 patients (61%) received a BPP and 163 received (39%) a polyester patch. The mean age was 70.2 ± 8.7 years and 67% were male. The median follow-up time was 15 months (range, 12-27 months) for BPP and 42 months (range, 16-60 months) for polyester ($P < .001$). Postoperative hematoma (≤30 days) was significantly lower in the BPP cohort (2% BPP vs 6% polyester; $P = .047$). No other significant differences on short-term outcomes were found. Univariable Cox regression analyses showed no significant differences between the effect estimates of polyester and BPP on TIA or CVA ($P = .106$), restenosis ($P = .211$), reintervention ($P = .549$), or all-cause mortality ($P = .158$). No significant differences were found after adjusting for confounders in the multivariable analyses: TIA or CVA ($P = .939$), restenosis ($P = .057$), reintervention ($P = .193$) and all-cause mortality ($P = .742$). Three patients with a polyester patch had patch infection compared with none of the patients in the group who received a BPP.

Conclusions: This large retrospective study showed comparable safety and durability of both BPP and polyester suggesting that both patch types can be safely applied for CEA with patch angioplasty. Patch infection was rare and was absent in the BPP group. (J Vasc Surg 2023;77:559-66.)

Keywords: Carotid endarterectomy; Patch angioplasty; Bovine pericardial patch; Polyester

Stenosis of the internal carotid artery is one of the major causes of ischemic stroke.[1,2] To decrease the risk of stroke in both symptomatic and asymptomatic carotid stenosis carotid endarterectomy (CEA) with patch angioplasty may be performed. For patients undergoing CEA, routine patch closure is recommended, rather than primary closure.[3] A variety of materials are available, including autologous veins (eg, the saphenous vein), synthetic patches (eg, polytetrafluoroethylene or polyester), and biological patches (eg, bovine pericardial patches [BPP]).[4-6] However, the choice of which patch to use remains a matter of debate.[3] Although saphenous vein

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patches are often used and deliver good results, many disadvantages exist, resulting in a prolonged intervention time. Further, an additional incision must be made, which in turn increases the risk of developing wound complications at the harvest site, especially in patients with vascular disease owing to poor wound healing and a higher risk of infection.[1,7] These limitations can be bypassed when synthetic or biological patches are used, which are usually readily available. However, synthetic patches may be more thrombogenic, carry a higher risk of infection, and have an increased risk of bleeding when compared with autologous venous patches.[8] In recent years, the use of BPP has become more popular. A recently published network meta-analysis did not find significant differences between BPP and polyester patch regarding 30-day stroke or death rate and late restenosis.[9] In 2021, a Cochrane review demonstrated that BPP material may decrease the incidence of fatal stroke, infection, and death when compared with other graft materials.[1] However, the quality of evidence was low owing to the small numbers of events. Although these studies showed promising short-term outcomes for BPP, long-term outcomes for most patch types are still unknown and there are insufficient high-quality data to make recommendations in guidelines. Therefore, the aim of our study was to evaluate the difference between BPP and polyester in long-term follow-up outcomes (ie, transient ischemic attack [TIA] or cerebrovascular accident [CVA], restenosis, reintervention, all-cause mortality, or patch infection in patients who received a CEA with patch angioplasty).

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective cohort study
- **Key Findings:** Cox analyses showed no significant differences between carotid endarterectomy with a bovine pericardial patch (n = 254) or polyester (n = 163) on the following outcomes with long-term follow-up: transient ischemic attack or cerebrovascular accident, restenosis, reintervention, and all-cause mortality. Patch infection was rare and completely absent in the bovine pericardial patch group.
- **Take Home Message:** Long-term outcomes of bovine pericardial patch and polyester patch angioplasty during carotid endarterectomy are comparable.

METHODS

Study design. All consecutive patients who underwent primary CEA with patch closure using bovine pericardium or polyester between January 2010 and December 2020 at our tertiary referral center were included in this study. In 2015, BPP was introduced as an alternative for polyester. In 2016, BPP surpassed polyester as the most used patch for CEA in our center. Patients who underwent CEA with primary closure or closure with other patch types than BPP/polyester were excluded from the current study.

The institutional review board approved dispensation in accordance with Dutch law on patient-based medical research obligations (registration no. METc 2021/493). Consequently, informed consent was not obtained. All patient-related data were processed anonymously and stored electronically in agreement with the Declaration of Helsinki – Ethical principles for medical research involving human subjects.[10]

Patient characteristics and definitions. Baseline characteristics that were obtained from the electronic patient file included age at surgery in years, sex, body mass index, tobacco use, hypertension, hyperlipidemia, diabetes mellitus, and cardiac, pulmonary, and renal disease. Tobacco use was defined as current use or less than 1 year of abstinence. Hypertension, hyperlipidemia, cardiac, pulmonary, and renal disease were classified by the Society for Vascular Surgery (SVS) system (classes 0-3) according to the Ad Hoc Committee on Reporting Standards.[11,12] These comorbidities were scored positive if the status was 1 or higher. Symptomatic carotid stenosis (>50% internal carotid artery stenosis) was defined as ipsilateral CVA, TIA, or ocular symptoms (amaurosis fugax) 6 or fewer months before surgery. Asymptomatic stenosis was defined as asymptomatic internal carotid artery stenosis of more than 50% or as symptomatic carotid stenosis more than 6 months earlier (following the reporting standards for carotid interventions from the SVS and the European Society for Vascular Surgery guidelines).[3,13] Furthermore, symptoms at presentation, antiplatelet therapy, anticoagulation use, and statin use were collected. Grade of preoperative ipsilateral stenosis as seen on the duplex ultrasonography was noted. We used the following peak systolic velocities for the internal carotid artery: less than 125 cm/s for a less than 50% stenosis, 125 cm/s or more for 50% to 69% stenosis, 230 cm/s or more for 70% to 89% stenosis, and 400 cm/s or more for more than 90% stenosis (but not near occlusion).[14] The presence of contralateral occlusion of the internal carotid artery, as shown on duplex ultrasound examination, was noted.

Surgical procedure. Details of the surgical procedure have been published previously.[15,16] Before surgical treatment, patients received a statin and antiplatelet therapy (aspirin 100 mg/d and/or clopidogrel 75 mg/d) unless they were already using anticoagulants. Before clamping the carotid artery, patients received 5000 IU heparin intravenously. Intraoperative monitoring was performed using electroencephalography and transcranial Doppler imaging. Intraoperative shunting was performed if there were significant electroencephalography and/or transcranial

Doppler changes. Longitudinal arteriotomy was closed using a patch made of bovine pericardium (XenoSure Biologic Vascular Patch; LeMaitre, Burlington, MA) or polyester (Hemagard Carotid Patch; Getinge, Göteborg, Sweden). Protamine was not administered routinely. Postoperative monoantiplatelet or anticoagulant therapy was continued.

The following intraoperative variables were collected: operation side (left/right), type of anesthesia (regional or total), blood loss (mL), clamping time (minutes), shunting (yes/no), and patch type (BPP or polyester).

Postoperative length of hospital stay was noted. Standard antiplatelet therapy was given after CEA and surveillance duplex was performed 6 weeks postoperatively, followed once a year thereafter.

Outcome. The primary outcome measure was the occurrence of ipsilateral TIA/CVA during follow-up. This was based on evaluation by a neurologist and confirmation with cerebral imaging. Secondary outcomes included ipsilateral restenosis, ipsilateral reintervention, all-cause mortality, and patch infection. A peak systolic velocity threshold of more than 213 cm/s was used for diagnosing a restenosis of more than 50%.[3] Restenosis was scored positive if greater than 50%. Reintervention was defined according to the reporting standards for carotid interventions from the SVS as any postprocedural adjunctive maneuvers (ie, management of access site complications and management of postoperative stroke).[13] Patch infection was diagnosed according the Management of Aortic Graft Infection group classification (with at least one major criterion and one minor criterion from another category).[17]

In addition, short-term results within 30 days after CEA were also considered consisting of peripheral nerve damage, cardiac complication (myocardial infarction, angina pectoris, arrhythmia, or heart failure), delirium, urinary tract infection, wound infection, cervical hematoma (defined according to the SVS reporting standards for carotid interventions; SVS classes 1-3 were scored as positive), restenosis, TIA/CVA, and mortality.[13]

Statistical analyses. The distribution of continuous data was checked visually and supplemented by the Shapiro-Wilk test. The means and standard deviations of normal distributed continuous variables were calculated. Skewed distributed data were presented as median and interquartile range. The Student *t* test was used to compare normal distributed variables and Mann-Whitney *U* tests was used to compare variables with a skewed distribution between both patch types. Fisher's exact test was performed to compare categorical variables. Kaplan-Meier survival curves were plotted to visualize the effect of patch types on the primary and secondary outcome(s). Survival analysis was performed using Cox proportional hazard model with stepwise backward elimination calculating hazard ratio with the 95% confidence interval. Univariable Cox regression models were fitted to assess the crude effect of patch type on time to the occurrence of TIA/CVA, restenosis, reintervention, all-cause mortality, and patch infection. Subsequently, multivariable models were fitted for each outcome. The eligible variables for the adjusted models were selected whenever the univariable analyses between both patch types yielded a *P* value of less than .10. A variable was considered a confounder whenever the regression coefficient of the patch type changed by 10% or more. Confounders remained included in the multivariable models. Effect modification by diabetes mellitus and hypertension was also tested by including an interaction term (eg, Patch type × Diabetes mellitus and Patch type × Hypertension). All models yielded an estimated regression coefficient (β) with a corresponding hazard ratio and 95% confidence interval. The Cox regression model assumptions were tested and fulfilled. Statistical analysis was performed in R, version 4.0.5 (R Foundation for Statical Computing, Vienna, Austria), using the *survival*, *survminer*-, and *ggplot2*-packages. In all analyses, a *P* of less than .05 was considered statistically significant.

RESULTS

In total, 417 CEA patients were included. Two hundred fifty-four patients (61%) received a BPP and 163 received a polyester patch (39%). The mean age of the total group was 70.2 ± 8.7 and 67% were male. In Table I, baseline characteristics and comorbidities per patch type are listed. Patients with a polyester patch were more likely to have hypertension ($P = .004$), cardiac disease ($P = .001$), and renal disease ($P = .003$). No other differences between patch types were found.

There is a significant difference in the distribution of preoperative presentation (ipsilateral symptoms) in both groups ($P < .001$). There were no statistically significant differences in preoperative medication (antiplatelet, anticoagulation, and statin use), grade of stenosis, or presence of contralateral occlusion of the internal carotid artery (Table II).

Intraoperative variables are shown in Table II. Clamping time was 33 ± 8 minutes in BPP patients and 34 ± 9 in patients with a polyester patch ($P = .165$). Operation time was significantly longer in the group with CEA with polyester compared with BPP, at 184 ± 32 compared with 148 ± 35 minutes ($P < .001$). Thirty-one BPP patients (12%) underwent shunting compared with 15 polyester patients (9%) ($P = .333$).

The median postoperative length of hospital stay was 3 days (3-4 days) for both patch types. The median follow-up time was 15 months (12-27 months) for BPP and 42 months (16-60 months) for polyester ($P < .001$). Other postoperative characteristics are shown in Table II.

Table I. Patient characteristics associated with type of patch

Patient characteristics	Bovine	Polyester	*P* value
No. of patients	254 (61)	163 (39)	–
Age in years	69.6 ± 8.6	71.2 ± 8.9	.076
Sex (males)	169 (67)	111 (68)	.740
Body mass index, kg/m^2	27.2 ± 4.1	27.5 ± 5.1	.518
Tobacco use	115 (45)	63 (39)	.199
Hypertension	168 (66)	129 (79)	**.004**
Hyperlipidemia	211 (83)	139 (85)	.550
Diabetes mellitus	55 (21)	48 (29)	.072
Cardiac disease	85 (33)	80 (49)	**.001**
Pulmonary disease	37 (15)	30 (18)	.298
Renal disease	45 (18)	49 (30)	**.003**

Values are number (%) or mean ± standard deviation. Boldface entries indicate statistical significance.

Table II. Pre-, intra-, and postoperative characteristics

Characteristic	Bovine	Polyester	*P* value
Preoperative			
Ipsilateral symptoms			<.001
CVA	89 (35)	74 (45)	
TIA	101 (40)	51 (31)	
Ocular	57 (22)	22 (13)	
Asymptomatic	7 (3)	16 (10)	
Antiplatelet therapy	236 (93)	145 (89)	.160
Anticoagulation	32 (14)	26 (19)	.334
Statin use	219 (86)	137 (84)	.540
Stenosis grade			.680
<50%	1 (0)	0 (0)	
50%-69%	56 (22)	34 (21)	
70%-89%	176 (69)	119 (73)	
>90% (but not near occlusion)	21 (8)	10 (6)	
Contralateral occlusion	13 (5)	12 (7)	.400
Intraoperative			
Operation side (right)	112 (44)	70 (43)	.817
Intervention time (min)	148 ± 35	184 ± 32	<.001
Clamping time (min)	33 ± 8	34 ± 9	.165
Shunt use	31 (12)	15 (9)	.333
Postoperative			
Length of hospital stay, days	3 (3-4)	3 (3-4)	.580
Antiplatelet therapy	244 (96)	152 (93)	.252
Use of anticoagulation	33 (13)	24 (15)	.662

CVA, Cerebrovascular accident; *TIA*, transient ischemic attack.
Values are number (%), mean ± standard deviation or median (interquartile range written as first quartile-third quartile).

SHORT-TERM COMPLICATIONS (≤30 DAYS AFTER THE PROCEDURE)

Short-term (≤30 days) postoperative complications are summarized in Table III. Peripheral nerve damage occurred in 15 patients (6%) with BPP and 16 patients (10%) with a polyester patch (*P* = .136). Three patients (1%) with a BPP and 2 (1%) with a polyester patch developed a wound infection (*P* > .999). Clinical symptoms that were observed were fever, redness, localized pain, and swelling. All patients got antibiotic therapy (oral or

Table III. Postoperative short-term adverse outcomes

Characteristic	Bovine	Polyester	*P* value
Peripheral nerve damage	15 (6)	16 (10)	.136
Cardiac complication[a]	4 (2)	6 (4)	.198
Delirium	4 (2)	4 (2)	.717
Urinary tract infection	3 (1)	2 (1)	>.999
Wound infection	3 (1)	2 (1)	>.999
Cervical hematoma (class 1-3[b])	5 (2)	9 (6)	**.047**
Restenosis	3 (1)	2 (1)	>.999
TIA or CVA	7 (3)	10 (6)	.088
Mortality	0 (0)	2 (1)	.152

CVA, Cerebrovascular accident; *TIA*, transient ischemic attack.
Boldface entries indicate statistical significance.
[a]Myocardial infarction, angina pectoris, arrhythmia, or heart failure.
[b]According to the Society of Vascular Surgery Reporting standards for carotid interventions.

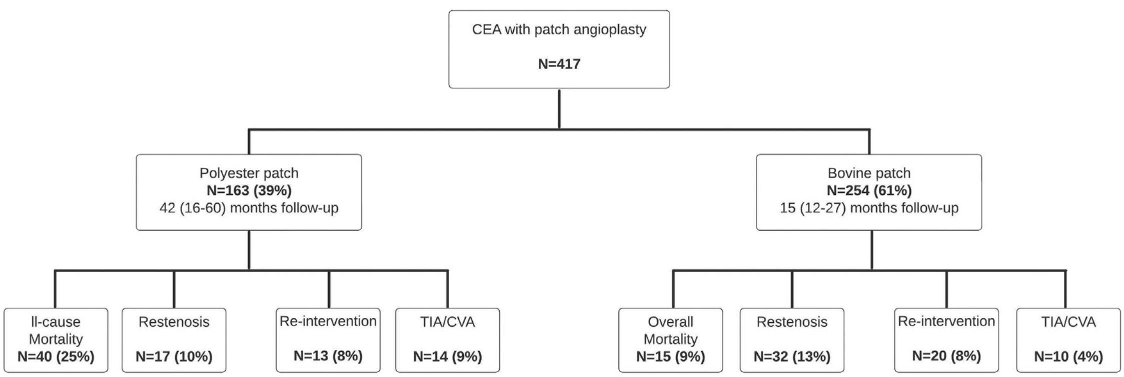

Fig 1. Total number of adverse events in patients with bovine pericardial patch (BPP) and polyester patch. *CEA*, Carotid endarterectomy; *CVA*, cerebrovascular accident; *TIA*, transient ischemic attack.

intravenous) and three patients (2 BPP and 1 polyester) were treated with incision and drainage. None of the patients developed a patch infection. There were significantly fewer BPP patients with a postoperative cervical hematoma compared with polyester patients (5 [2%] vs 9 [6%]; $P = .047$). There were no significant differences on short-term (ipsilateral) restenosis, TIA/CVA, and mortality between in BPP and polyester patients. Two patients (1%) versus 2 patients (1%) had a restenosis ($P > .999$), 7 (3%) versus 10 (6%) had a TIA or CVA ($P = .088$), and 0 (0%) versus 2 (1%) patients died within 30 days postoperative ($P = .152$).

Long-term outcomes. An overview of the number of adverse events per patch type is shown in Fig 1. The univariable Cox regression analyses showed no significant differences between the effect estimates of polyester and BPP on TIA/CVA ($P = .106$), restenosis ($P = .211$), reintervention ($P = .549$), and all-cause mortality ($P = .158$) (Table IV and Fig 2). After adjusting for confounders in the multivariable Cox regression analyses, no significant differences were found between patch types on TIA/CVA ($P = .939$), restenosis ($P = .057$), reintervention ($P = .193$), and all-cause mortality ($P = .742$) (Table IV). Effect modification by diabetes mellitus and hypertension was not observed in any model (all $P > .073$).

Peripheral nerve damage. One (7%) of the 15 BPP patients and 3 of the 16 polyester patch patients (19%) with (short-term) peripheral nerve damage had persistent symptoms at 1 year of follow-up ($P = .600$).

Patch infection. Three patients had a suspected graft infection in the total follow-up period. Two patients with a polyester patch presented with a pseudoaneurysm (after 57 and 37 months). The first patient underwent replacement surgery with an autologous venous patch and the second patient was treated conservatively. This patient was not fit enough for surgery and was treated with antibiotics alone. Diagnosis was based on clinical characteristics, intraoperative view, and imaging. Materials cultured during surgery were negative, however probably owing to long antibiotic use before surgery. The third patient presented (6 months postoperatively) with a fistula that extended from the (polyester) patch to the skin (Supplementary Fig, online only). This infected graft

Table IV. Univariable and multivariable Cox regression analyses of the effect of patch type on TIA/CVA, restenosis, reintervention, and all-cause mortality after 5 years of follow-up

Outcome	Predictor	β (95% CI)	HR (95% CI)	*P*
TIA or CVA (ipsilateral)	Polyester (ref: Bovine)	0.68 (−0.14 to 1.50)	1.97 (0.87 to 4.47)	0.106
	Polyester (ref: Bovine)[a]	−0.03 (−1.05 to 0.97)	0.96 (0.35 to 2.63)	0.939
Restenosis (ipsilateral)	Polyester (ref: Bovine)	−0.38 (−0.98 to 0.22)	0.68 (0.37 to 1.24)	0.211
	Polyester (ref: Bovine)[b]	−0.74 (−1.50 to 0.02)	0.48 (0.22 to 1.02)	0.057
Reintervention (ipsilateral)	Polyester (ref: Bovine)	−0.22 (−0.94 to 0.50)	0.80 (0.39 to 1.65)	0.549
	Polyester (ref: Bovine)[c]	−0.62 (−1.56 to 0.32)	0.54 (0.21 to 1.37)	0.193
All-cause mortality	Polyester (ref: Bovine)	0.45 (−0.17 to 1.07)	1.57 (0.84 to 2.93)	0.158
	Polyester (ref: Bovine)[d]	0.13 (−0.62 to 0.88)	1.13 (0.54 to 2.40)	0.742

CI, Confidence interval; *CVA*, Cerebrovascular accident; *HR*, hazard ratio; *ref*, reference; *TIA*, transient ischemic attack.
Tested for: age, sex, hypertension, diabetes mellitus, cardiac disease, renal disease, intervention time, symptoms ipsilateral, and shunt use.
[a]Adjusted for age, hypertension, renal disease, cardiac disease, symptoms ipsilateral, intervention time, and shunt use.
[b]Adjusted for intervention time.
[c]Adjusted for intervention time, and shunt use.
[d]Adjusted for age, diabetes mellitus, renal disease, intervention time, shunt use, and symptoms ipsilateral.

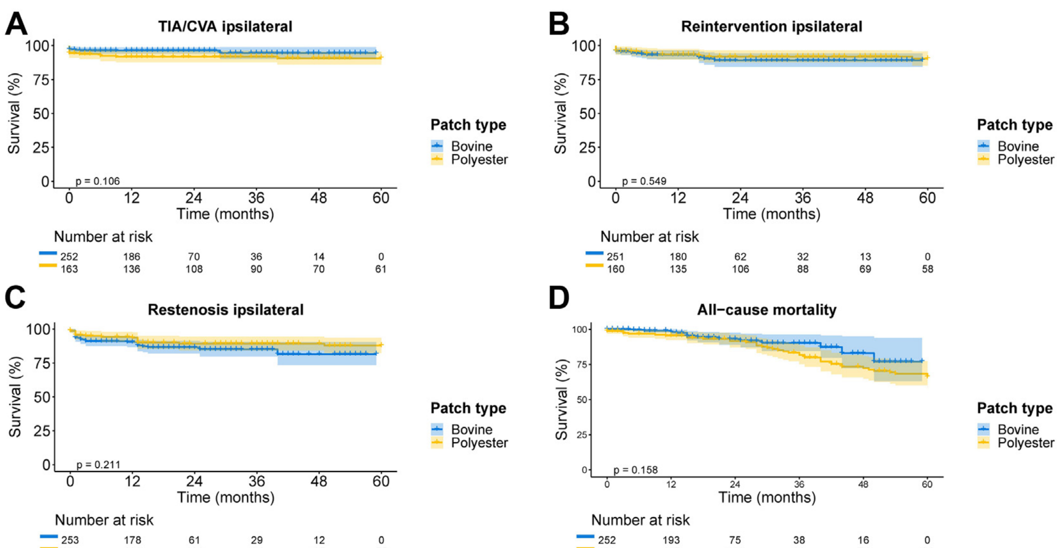

Fig 2. Survival curves per patch type for different outcomes. **A,** Transient ischemic attack (*TIA*)/cerebrovascular accident (*CVA*) ipsilateral. **B,** Reintervention ipsilateral. **C,** Restenosis ipsilateral. **D,** All-cause mortality.

was also replaced by an autologous venous patch. Intraoperative cultures were positive for *Staphylococcus aureus*.

DISCUSSION

In this retrospective study, we investigated the short- and long-term outcomes between BPP and polyester for CEA. With 417 CEA patients, of which 254 (61%) BPP, this is one of the largest retrospective studies comparing BPP with a synthetic alternative.[18] Our results showed that there were no statistically significant differences between the patch types regarding TIA/CVA, restenosis, reintervention, and all-cause mortality on multivariable analyses. These long-term outcomes without significant differences between both patch materials are comparable with previous published studies.[4,7,18,19]

Graft infection was rare and occurred in three patients with a polyester patch only; none of the BPP patients was affected. A similar lower infection rate (0.59%) of BPP compared with synthetic patches was found previously.[19] The hypothesis is that BPP is an acellular xenograft, making it less susceptible to infection compared with synthetic patches.[1] This acellular material of collagen may provide a natural environment for host cell migration and proliferation, which causes reendothelialization.[20] The possible infection resistant property was also demonstrated by several reports on BPP used in cardiovascular (graft) infection.[21-24]

Our study demonstrated that significantly fewer BPP patients has short-term (≤30 days) cervical hematoma compared with polyester patch patients ($P = .047$). A possible explanation for this difference may be the fact that the total suture line bleeding is significantly less with BPP compared with polyester patches (after adjustment for activated clotting time).[25] In this previously published study, bleeding at 3 and 4 minutes after carotid cross-clamp removal was observed. Furthermore, blood loss was quantified by weighing the sponge used to tamponade the bleeding. Suture line bleeding may be an explanation for the longer operation time that we found in the polyester patch group.

A previously published study did not show differences in 30-day hematoma (which required reintervention) between BPP and other materials (polyester, venous, primary closure, and other techniques).[18]

This study has limitations. First, the retrospective design of the study causes a lower level of evidence compared with prospective studies and causes a heterogenous sample with variety of follow-up periods. Because BPP was introduced in 2015, this type of patch had a shorter median follow-up time compared with polyester patch in our study. However, the medical management, diagnostic criteria, and surgical procedure remained the same throughout the study period (2010-2020). Because this study compares one type of BPP and one type of polyester patch, the results may differ when compared with patches from other manufacturers. Furthermore, the number of adverse events (longer term outcomes) were scarce, so comparison between two groups requires a large amount of patients to decrease type II error. In particular, the trends observed on the differences of short-term TIA/CVA ($P = .088$) and restenosis ($P = .057$) in the multivariable analysis deserve to be further investigated using a larger sample size. However, this is one of the largest retrospective studies comparing BPP with polyester patches on longer term outcomes.

CONCLUSIONS

This study showed comparable safety and durability of both BPP and polyester, making both options acceptable for CEA with patch angioplasty. Patch infection was rare and only three patients with a polyester patch were affected, while absent in the BPP group. In the short term, there were significantly fewer BPP patients with a postoperative hematoma compared with polyester patients. The choice between patch types remains depending on the experience of the surgical team.[3] Future studies with a larger sample will have to determine if there is a difference in the risk of getting (graft) infection between BPP and polyester.

AUTHOR CONTRIBUTIONS

Conception and design: DL, BG, CZ, BS
Analysis and interpretation: DL, BG, SD, GDB, CZ, BS
Data collection: DL, RL
Writing the article: DL, BG, CZ, BS
Critical revision of the article: DL, BG, RL, SD, GDB, CZ, BS
Final approval of the article: DL, BG, RL, SD, GDB, CZ, BS
Statistical analysis: DL, BG
Obtained funding: DL, CZ, BS
Overall responsibility: DL

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Supplementary Fig (online only). Fistula that extended to the skin of the patient.