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## Short- and long-term outcomes following biological pericardium patches versus prosthetic patches for carotid endarterectomy: A retrospective bicentric study

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1 Title :

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22

23 ABSTRACT

24 INTRODUCTION: Currently, there are various types of patches available on the market for  
25 carotid endarterectomy (CEA) with enlargement angioplasty, prosthetic and biological  
26 patches including bovine pericardial patches. Despite the increasing use of these biological  
27 patches, there is little data in the literature comparing the results of these two types of  
28 patch. The purpose of this study was to compare the short- and long-term results of bovine  
29 pericardium patches (BPP) with prosthetic patches (PP) in carotid thromboendarterectomy.

30 METHODS: This study presents a retrospective analysis of all CEAs performed at Montpellier  
31 and Nîmes University Hospitals (France) in 2014 and 2015. Patients who underwent eversion  
32 were excluded. Pre-, per- and post-operative clinical and doppler ultrasound results were  
33 collected and analyzed. The primary endpoint was the comparison of the restenosis rate  
34 between the BPP and the PP group. Secondary endpoints were the analysis of restenosis risk  
35 factors (type of patch, gender, renal failure, smoking, diabetes, arterial hypertension,  
36 dyslipidemia and redo surgery were analyzed); the comparison of morbidity-mortality and  
37 infection between BPP and PP group and the comparison of morbidity-mortality between  
38 symptomatic and asymptomatic stenosis.

39 RESULTS: In total, 342 CEAs were performed, of which 168 (49%) with BPP and 174 (51%)  
40 with PP. Median follow-up was 30 months (IQR=24). The stroke rate at Day 30 was 3.22%  
41 and mortality at Day 30 was 1.86%. There was no significant difference between groups  
42 concerning anyone of the variables of interest. At the end of follow-up, the restenosis rate  
43 >50% was 7.31% (6.45% BPP group vs 8.22% PP group, p=.55). The severe restenosis rate  
44 (>70%) was 4.65% (5.16% BPP group vs 4.11% PP group, p=.79). The univariate analysis  
45 identified renal failure (Odds Ratio = 2.69) as the main risk factor. The postoperative  
46 infection rate was 1.17% (0.59% BPP group vs 1.75% PP group, p=.62).

47 CONCLUSION: The rates of stroke and post-operative death, bleeding, infection and  
48 restenosis are comparable between bovine pericardium patches and prosthetic patches in  
49 our study. The use of prosthetic or biological patches seems to deliver comparable  
50 outcomes. Further studies on larger samples are required.

51

52 KEYWORDS: carotid endarterectomy, restenosis, bovine pericardium patch, prosthetic patch

53

54

55

## 56 **INTRODUCTION**

57 Strokes and their prevention are a major challenge to public health in industrial countries,  
58 with more than 140 000 strokes per year in France.<sup>1</sup> Ischemic strokes represent 80% of all  
59 strokes, and carotid stenosis is responsible for these in approximately 20% of cases.<sup>2</sup> Carotid  
60 endarterectomy (CEA) in combination with medical therapy is indicated to prevent strokes in  
61 asymptomatic carotid stenosis (60-99% of stenosis degree) or recurrence of symptoms in  
62 symptomatic carotid stenosis (50-99% of stenosis degree).<sup>3</sup> More than 13 000 CEAs are  
63 performed annually in France.

64 CEA can be performed either by the eversion technique or the standard technique with  
65 patch closure according to surgeon's preference.<sup>3</sup> Over the years, several kind of patches  
66 have been used: prosthetic (Dacron or PTFE) and biological including saphenous vein and  
67 bovine pericardium. CEA with bovine pericardium patches (BPP) was first described by Biasi  
68 in 1996.<sup>4</sup> Recently, increasing numbers of surgeons have been choosing to use BPP,  
69 attracted by its biocompatibility and its low rate of infection, thrombogenicity and operative  
70 bleeding.<sup>5-6</sup> There is no proven significant difference between the different materials on

71 short- and long-term results.<sup>7</sup> However literature comparing BPP with prosthetic patches  
72 (PP) on short- and long-term remains fairly limited.<sup>6-8-9</sup>

73 The aim of this study was to retrospectively evaluate the short- and long-term results of CEA  
74 with prosthetic versus biological bovine pericardium patching. In addition, the risk factors for  
75 restenosis were studied.

76

77

## 78 **METHODS**

### 79 *Study group*

80 This retrospective study was conducted from January 1<sup>st</sup>, 2014 to December 31<sup>st</sup>, 2015. The  
81 follow-up was continued until December 31<sup>st</sup>, 2018. All patients who had undergone a CEA  
82 surgery with patch angioplasty at the University Hospitals of Montpellier and Nîmes in  
83 France were enrolled. This study was approved by the Institutional Review Board of  
84 Montpellier University Hospital. A consent form (with information and a non-objection to  
85 participate in the study clause) was sent to each patient. Patients who underwent eversion  
86 CEA were excluded, all eversion were realized without patch. Surgery was performed under  
87 general anesthesia and a vascular shunt was most often used. Before 2014 PP were  
88 exclusively used. From 2014, BPP were introduced and became standard practice at the end  
89 of 2015. The choice of type of patch was left to the surgeon's preference. BPP was used for  
90 redo operations on a previous CEA with PP closure.

91 For the PP group, Dacron patches: Hemacarotid (Maquet®), Hemacarotid patch  
92 (Intervascular®) and polyurethane patches: Vascular patch (B.Braun®) were used. For the  
93 BPP group, bovine pericardium patch Xenosure (LeMaitre®) were exclusively used.

94 Data of the CEA, demographic factors and comorbid conditions were collected from patient  
95 medical files. The Best Medical Therapy (BMT) was defined as an antiplatelet therapy with  
96 statins.

#### 97 *Follow up*

98 Patients were usually seen at the control visit at 1 or 3 months with a doppler ultra sound  
99 (US). General practitioner or angiologist were contacted by telephone following a call  
100 questionnaire for patients with less than 30 months of follow-up. Data about clinical status  
101 and doppler US were gathered. Velocimetric criteria and percentage stenosis according  
102 NASCET methods were coupled for the US study in both centers.<sup>10</sup>

103 The short-term outcomes were defined as the first post-operative month outcomes, long-  
104 term outcomes gathered all outcomes after the first month.

105 The short- and long-term outcomes of the two groups, PP and BPP, were collected and  
106 compared. The patients lost to follow-up were not included in the outcomes' analysis.

107 The cranial nerve injury was defined as a clinical manifestation of cranial nerve injury  
108 occurring after the surgery without pre-existing palsy.

#### 109 *Statistical analysis*

110 The statistical analysis was made using Fischer or Chi2 test for binary qualitative variables.

111 Student and Wilcoxon tests were used to compare qualitative and quantitative variables.

112 The software SAS, 9.2 version, was used for the statistical analysis. The cut-off of significance  
113 was  $p < .05$ .

114 The risk factor analysis of restenosis used odds ratio calculation. The analyzed factors have  
115 been chosen according the ones previously described in the literature. They are gender, type  
116 of patch, diabetes, dyslipidemia, arterial hypertension, smoking, renal failure (define as a  
117 glomerular filtration rate of less than 60mL/min/1.73m<sup>2</sup>) and redo CEA.

118 *Objective*

119 The primary endpoint was the comparison by type of patch of post-operative restenosis >  
120 50% rate. Severe restenosis was defined as > 70% at the control ultrasound examination.  
121 Early restenosis was defined as restenosis diagnosed before the 18<sup>th</sup> month. The restenosis  
122 data was considered as missing if there was no ultrasound checkup examination after a  
123 minimum of one month. The secondary endpoints were the analysis of risk factors of  
124 restenosis by a univariate method, the comparison by kind of patch of hemorrhagic event,  
125 morbidity-mortality at one month, infection, and the comparison by stenosis character of  
126 morbidity-mortality.

127 Analysis of risk factors for restenosis > 50% was presented by odds ratios.

128

129 The reporting of this study conforms to the STROBE (Strengthening the Reporting of  
130 Observational Studies in Epidemiology) statement.

131

132

## 133 **RESULTS**

134 *Descriptive analysis*

135 During the study period, 345 patients having undergone CEAs with patch angioplasty were  
136 treated. Three patients refused to participate to the study and were excluded. Of the 342  
137 included patients: 168 receiving BPP angioplasty and 174 PP angioplasty. Concerning the  
138 type of PP, Dacron was used for 122 CEAs, polyurethane for 50 CEAs, and data were missing  
139 for 2 CEAs. These two CEAs were included in the PP group for the analysis. Mean age was 73  
140 years at the time of surgery and the majority of patients were male (73%). The population  
141 characteristics are described in Table I.

142

143 The BMT, was preoperatively prescribed in 64% of cases. Symptomatic stenosis represented  
144 43% of all CEAs performed. A carotid shunt was used in more than 95% of cases (96.4% BPP  
145 group vs 94.8% PP group,  $p=0.47$ ).

146 The two groups were similar regarding pre-operative characteristics apart from the  
147 frequency of ACE inhibitor medication, which was greater for the PP group and frequency of  
148 a history of ipsilateral carotid surgery, which was higher in the BP group.

149 The median duration of clinical follow-up was 30 months (IQR=24) and 22 months (IQR=27)  
150 for doppler US follow-up. At one month there were 6 deaths (3 carotid related causes and 3  
151 extra neurologic causes) and 20 patients lost to follow-up. At one year there were 19 deaths  
152 and 61 patients lost to follow-up.

153

#### 154 *Primary endpoint*

155 The overall > 50% restenosis rate was 7.31% (22 cases). There was no significant difference  
156 between groups (6.45% BPP group vs 8.22% PP group,  $p=0.56$ ). The restenosis > 70% rate  
157 was 4.65% without significant difference between groups (5.16% BPP group vs 4.11% PP  
158 group,  $p=0.79$ ). Early restenosis represented the majority of the restenosis observed (90.9%,  
159  $n=20/22$ ). At Duplex US control follow-up we observed a regression of lesion in 18.2% of  
160 cases of restenosis > 50% ( $n=4/22$ ). All of patients presenting a regression followed the BMT.  
161 Severe restenosis treatment per patient is detailed in Table II.

162

#### 163 *Secondary endpoints*

164 In the univariate analysis, with a Chi2 test, renal failure was the main risk factor for  
165 restenosis (5.5% vs 13.6%,  $p=0.03$ , OR=2.70, IC 1.09-6.62). We observed a near significant



166 increase of restenosis rate on patients treated by statins in preoperatory (9.0% vs 3.4%,  
167  $p=0.08$ ). The others risk factors studied (gender, smoking status, diabetes, obesity, arterial  
168 hypertension) had no significant odds ratios.

169 There were no differences in all the short-term outcomes between the two groups (Table  
170 III). The rate of hemorrhagic complications with surgical revision was 4.39% (4.76% BPP vs  
171 4.02% PP,  $p=0.74$ ). The stroke/mortality rate at postoperative day 30 was not significantly  
172 different between groups (2.48% for BPP vs 6.32% for PP,  $p=0.15$ ). The rate of acute  
173 coronary syndromes at Day 30 was 0.88% which correspond to three patients.

174 Furthermore, there was no significant difference in morbidity-mortality rates between  
175 symptomatic versus asymptomatic carotid stenosis (5.52% vs 2.56%,  $p=0.25$ ), regardless of  
176 the type of patch.

177 The global infection rate was 1.17% with only four events during follow-up (PP=3, BPP=1),  
178 There was no significant difference between the two groups. The different cases were  
179 described in the Table IV.

180 The overall rate of cranial nerve injuries (CNIs) was 6.73% ( $n=23$ ). This rate was higher for  
181 patients with a medical history of Ear-Nose-Throat neoplasia (22.2%), cervical radiotherapy  
182 (20%) and redo CEA for carotid restenosis (16.7%). The majority of these lesions were not  
183 permanent ( $n=15/23$ , 56.5%).

184

## 185 **DISCUSSION**

186 Our study presents the retrospective results of 168 CEAs with BP in comparison to 174 CEAs  
187 with PP. It is the second largest retrospective study on this specific topic after the study from  
188 the Mayo Clinic based on more than 800 patients.<sup>9</sup> Two small prospective studies have been  
189 described in the medical literature.<sup>6-8</sup> At the end of follow-up with Duplex US, the restenosis

190 > 50% rate (7.3%) and the severe restenosis rates (4.6%) were equivalent to those described  
191 by a meta-analysis gathered from randomized trials.<sup>11</sup> Indeed, in the study of Kumar and al.  
192 restenosis > 70% rate was 4.1% after patched CEA at a median of 35 months. There was no  
193 significant difference in restenosis > 70% rate between the two groups (4.11% PP group vs  
194 5.16% BP group, p=.79). These results seem comparable to the those found in the two  
195 previous studies describing this outcome : 2% of restenosis >70% rate for the BPP at two  
196 years in the study of Stone ; 11.0% of restenosis >50% rate for the BPP at ten years in the  
197 study of Oldenburg.<sup>8-9</sup>

198 Concerning the risk factors for restenosis, we observed that renal failure was the only  
199 proved risk factor. This risk factor have already been stressed.<sup>12</sup>

200 Regarding the evolution of restenosis, we found more than 15% (18.4%) of spontaneous  
201 regression under antiplatelet therapy combined with statins. Statins appeared to have a  
202 protective or reducing effect on restenosis.<sup>13</sup> Oldenburg described a better 10-year survival  
203 rate for patients following a post-operative therapy with statins.<sup>8</sup>

204 Although the infection in the two groups was too low to determine statistically significant  
205 results, the lower rate seen in the BPP group could warrant preferring this patch to avoid  
206 post-operative infection. The infection rate was 0.59% for the BPP group, which is lower  
207 than that described for prosthetic patch in the literature.<sup>14</sup> Similar to aortic infection  
208 surgery, this pericardium patch clearly seems to have biocompatibility qualities.<sup>15-16</sup>

209 The Day 30 morbidity-mortality rate for symptomatic and asymptomatic stenosis (5.52% and  
210 2.56%) are in accordance with the recommended guidelines.<sup>3</sup>

211 The Texakalidis et al. meta-analysis published in 2018 comparing more than 3 000 patients  
212 did not shown any difference in short- or long-term complications depending on the type of

213 patch material used. However only two of the 18 collated studies included a pericardium  
214 patch. Our study supports the safety of using the BPP.

215

216 The main limitation of this work is the small number of participants. Indeed, restenosis is a  
217 rare long-term complication. A comparative study on this complication requires a larger  
218 sample of patients. Another limitation is the retrospective nature, which defines a lower  
219 level of evidence than a prospective design and is responsible for an important number of  
220 patients lost at follow-up despite the call questionnaire and for the disparities in the length  
221 of follow-up.

222

223

## 224 **CONCLUSION**

225 Our retrospective study does not report any significant differences in morbidity-mortality  
226 rates at short- or long-term for using the biological pericardium patch or the prosthetic  
227 patch. More particularly, the use of the pericardium patch is not associated with an increase  
228 in restenosis. Therefore the choice of the type of patch should be left to the preference of  
229 the surgeon as described in guidelines.<sup>3</sup> Further research with higher number of patients  
230 included must be realized.

231

## 232 **CONFLICT OF INTEREST**

233 None

234

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236 None

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280 **Table I.** Patient characteristics. Data are presented as average  $\pm$  standard deviation or number (%)

282 **Table II.** Management of severe restenosis

283

284 **Table III.** Short- and long-term outcomes following CEA. Data are presented as number (%)

285

286

287 **Table IV.** Post-CEA infections

288

**Table I.** Patients' characteristics. Data are presented as average  $\pm$  standard deviation or number (%)

	total (n=342)	BPP (n=168)	PP (n=174)	p
age average in years, SD	73 ( $\pm$ 9.7)	71 ( $\pm$ 9.3)	73 ( $\pm$ 9.9)	.08
male gender, n (%)	250 (73.1)	125 (74.4)	125 (71.8)	.63
Comorbidities	n (%)			
Active smoking	76 (22.2)	102 (60.7)	102 (58.6)	.74
Hypertension	278 (81.3)	135 (80.4)	143 (82.2)	.68
Diabetes mellitus	137 (40.1)	69 (41.1)	68 (39.1)	.74
Coronary artery disease	134 (39.2)	64 (38.1)	70 (40.2)	.74
Dyslipidemia	164 (48.0)	77 (45.8)	87 (50.0)	.45
Peripheral artery disease	71 (20.8)	40 (23.8)	31 (17.8)	.18
Obesity	68 (20.0)	32 (19.0)	36 (20.7)	.79
Chronic renal failure	78 (22.8)	39 (23.2)	39 (22.4)	.89
ENT neoplasia	10 (2.92)	4 (2.38)	6 (3.45)	.75
Cervical radiotherapy	6 (1.75)	1 (0.59)	5 (2.87)	.22
Ipsilateral carotid surgery history	14 (4.09)	12 (7.14)	2 (1.15)	.006
Medical therapy	n (%)			
Antiplatelet therapy	292 (85.4)	143 (85.1)	149 (85.6)	1
Statin	239 (69.9)	115 (68.5)	124 (71.2)	.64
Antiplatelet therapy + statin	217 (63.5)	106 (63.1)	111 (63.8)	.91
Beta-blocker	135 (39.5)	68 (39.1)	67 (39.9)	.91
ACE inhibitor	98 (28.6)	37 (22.0)	61 (35.1)	.01
Stenosis character	n (%)			
Symptomatic < 6 months	146 (42.7)	64 (38.1)	82 (47.1)	.1

**Table II.** Management of severe restenosis

Patient	Type of patch	Time until occurrence (months post-operative)	Restenosis percentage by US (velocity)	Clinical status	Kind of treatment	Outcomes after the latest treatment and follow-up delay
I	PU	3 months	70%	NSym	CAS Tigriss	Re-restenosis carotid by-pass at 18 months
II	PU	12 months	90%	NSym	None	Occlusion at 3 years
III	PU	6 months	70%	NSym	Redux CEA PPB	Permeability at 6 months
IV	BP	3 months	80%	NSym	CAS Acculink	Permeability at 1 year
V	BP	12 months	60 then 80%	NSym	CAS Wall stent	Re-Restenosis 60% Stable at 2 years
VI	BP	12 months	80%	NSym	CAS Wall stent	Permeability at 8 months
VII	BP	12 months	80%		Carotid by-pass (saphenous)	Permeability at 15 months
VIII	BP	12 months	75%	Sym	Redux CEA PPB	Permeability at 8 months
IX	BP	6 months	80%	NSym	CAS Wall stent	Re-restenosis 65% at 1 year. Stable at 18 months
X	Dac	6 months	70%	NSym	None	Stable at 2 years
XI	Dac	4 months	80%	NSym	Carotid by-pass (PTFE)	Permeability at 3 years
XII	Dac	2 years	70%	NSym	CAS uk stent	Permeability at 6 months
XIII	BP	6 months	70%	Sym	CAS uk stent	Permeability at 1 year
XIV	BP	12 months	70%	NSym	None	Stable at 3 years

PU: polyurethane; Dac: Dacron; Sym: symptomatic; NSym: nonsymptomatic; CAS: carotid artery stenting; uk stent: unknown stent

**Table III.** Short- and long-term outcomes following CEA. Data are presented as number (%)

	Total (n=342)	BPP (n=168)	PP (n=174)	p
Restenosis				
>50%	22 (7.31)	10 (6.45)	12 (8.22)	.56
>70%	14 (4.65)	8 (5.16)	6 (4.11)	.79
Early restenosis	20 (6.64)	9 (5.81)	11 (7.43)	.65
Hemorrhagic complication with surgical revision	15 (4.39)	8 (4.76)	7 (4.02)	.74
Stroke D30	11 (3.22)	3 (1.86)	8 (4.60)	.14
Death D30	6 (1.86)	2 (1.24)	4 (2.48)	.37
Stroke + death D30	14 (4.09)	3 (2.48)	11 (6.32)	.15
Acute Coronary Syndrome D30	3 (0.88)	1 (0.61)	2 (1.15)	1
Infection	4 (1.17)	1 (0.59)	3 (1.75)	.62
Cranial nerve injury	23 (6.73)	13 (7.74)	11 (6.32)	.61

**Table IV.** Post-CEA infections

Patient	Kind of patch	Post-operative delay	Infection agent	Treatment
I	BPP	10 months	Staph. epidermidis	Saphenous by-pass
II	PP	3 years	Staph. capitis	CEA with BPP
III	PP	Day 7	Serratia marcescens + Propionibacterium acnes	CEA with BPP
IV	PP	Day 20	Unknown	CEA with BPP