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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 :

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

5

6 Authors :

7 Freycon-Tardy Léonore¹, doctor of general surgery, leonore.freycontardy@chu-nimes.fr

8 Faure Elsa¹, doctor of vascular surgery, elsa.faure@chu-nimes.fr

9 Peyre-Costa D², d-peyre@chu-montpellier.fr

10 Canaud L³, professor in vascular surgery, l-canaud@chu-montpellier.fr

11 Branchereau P¹, doctor in vascular surgery, pascal.branchereau@chu-nimes.fr

12 Marty-Ané CH³, professor in thoracic and cardio-vascular surgery, ch-marty_ane@chu-
13 montpellier.fr

14 Alric P³, professor in vascular surgery, p-alric@chu-montpellier.fr

15 Picard E¹, doctor in vascular surgery, eric.picard@chu-nimes.fr

16

17 ¹ Department of Vascular and Thoracic Surgery, CHU Nimes, France

18 ² Department of Research and Medical Information, CHU, Montpellier, France

19 ³ Department of Thoracic and Vascular Surgery, CHU Arnaud de Villeneuve, Montpellier, France

20

21 Corresponding author: Leonore.FREYCONTARDY@chu-nimes.fr

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

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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.¹ Ischemic strokes represent 80% of all
59 strokes, and carotid stenosis is responsible for these in approximately 20% of cases.² 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).³ 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.³ 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 1996.⁴ 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.⁵⁻⁶ There is no proven significant difference between the different materials on

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

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 1st, 2014 to December 31st, 2015. The
81 follow-up was continued until December 31st, 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.¹⁰

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 $60\text{mL}/\text{min}/1.73\text{m}^2$) 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 18th 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.⁹ Two small prospective studies have been
189 described in the medical literature.⁶⁻⁸ 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.¹¹ 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.⁸⁻⁹

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.¹²

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.¹³ Oldenburg described a better 10-year survival
203 rate for patients following a post-operative therapy with statins.⁸

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.¹⁴ Similar to aortic infection
208 surgery, this pericardium patch clearly seems to have biocompatibility qualities.¹⁵⁻¹⁶

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.³

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.³ 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 |