

Bovine Pericardium vs Dacron for Patch Angioplasty After Carotid Endarterectomy

A Prospective Randomized Study

Brian J. Marien, MD; Joseph D. Raffetto, MD; Craig S. Seidman, MD; Wayne W. LaMorte, MD, PhD, MPH; James O. Menzoian, MD

Hypothesis: Bovine pericardium (BP) demonstrates improved intraoperative hemostasis and equivalent perioperative morbidity compared with Dacron when used as patch material for angioplasty following carotid endarterectomy.

Objective: To prospectively compare BP and Dacron patch angioplasty after carotid endarterectomy in a randomized fashion.

Methods: Ninety-five consecutive primary carotid endarterectomies were performed in a prospective randomized fashion in 92 patients. Fifty-one procedures were performed using BP and 44 using Dacron. Intraoperative suture line bleeding was subjectively evaluated by observing bleeding at 3 and 4 minutes following carotid cross-clamp removal and then objectively weighing the sponge used to tamponade bleeding during these time intervals. Perioperative morbidity, including cervical wound hematoma, transient ischemic attack, and stroke, and perioperative mortality were recorded. Statistical analysis was performed using paired *t* tests, χ^2 analysis, Fisher exact test, or multiple linear regression as appropriate.

Results: Suture line bleeding at 3 minutes was present in 7 (14%) of 51 patients in the BP group and 24 (55%) of 44 patients in the Dacron group ($P < .001$). Suture line bleeding evaluated at 4 minutes was present in 2 (4%) of 51 patients in the BP group and 13 (30%) of 44 patients in the Dacron group ($P = .001$). Net \pm SEM sponge weight (total intraoperative suture line bleeding) was 6.25 ± 0.55 g in the BP group and 16.34 ± 1.85 g in the Dacron group ($P < .001$). Total suture line bleeding was significantly affected by activated clotting time; however, multivariate analysis demonstrated that bleeding was significantly less with BP ($P < .001$) even after adjusting for differences in activated clotting time.

Conclusions: Bovine pericardium demonstrated a statistically significant decrease in intraoperative suture line bleeding compared with Dacron. Handling characteristics were judged by the surgeons to be superior for BP. Therefore, we believe BP may be an alternative to Dacron when performing patch angioplasty of the carotid artery after endarterectomy.

Arch Surg. 2002;137:785-788

THE EFFECTIVENESS of carotid endarterectomy in symptomatic and asymptomatic individuals for the prevention of cerebral infarction has been clearly demonstrated in multiple prospective randomized clinical trials.¹⁻⁵ However, the method of arteriotomy closure, primary vs patch, has been a matter of considerable debate.⁶⁻¹¹ Recent articles¹²⁻¹⁶ indicate patch closure is independently associated with a decreased incidence of recurrent stenosis compared with primary closure following carotid endarterectomy. However, the type of patch material remains a subject of controversy. Autologous vein, homologous vein, polytetrafluoroethylene, and Dacron are the various patch angioplasty materials commonly used.¹⁷⁻²⁷ No consistently

significant difference in terms of perioperative morbidity, mortality, and incidence of recurrent stenosis has been demonstrated.^{19,27}

Processed bovine pericardium (BP) has been introduced as an alternative to the aforementioned patch materials. It is now being used for reconstruction of the carotid, renal, and peripheral vessels. Bovine pericardium has been used as a patch material in intracardiac procedures for more than 2 decades with excellent results. It exhibits characteristics of an ideal patch material, including similarity in consistency to native artery, nonthrombogenicity, sufficient mechanical strength, biocompatibility, off-the-shelf availability, and cost comparable to other synthetic materials. It resists suture line bleeding, requires no preclotting, supports endothe-

From the Section of Vascular Surgery, Boston Medical Center, Boston, Mass.

PATIENTS AND METHODS

Ninety-two patients underwent 95 consecutive primary carotid endarterectomies at the Boston Medical Center, Boston, Mass. Using randomization based on the last number of the patients' medical record numbers, 51 patients received BP patches (odd number) and 44 patients received Dacron patches (even number). Patients scheduled for combined carotid endarterectomy and coronary artery bypass grafting and additional operations for recurrent disease were excluded from the study.

All patients underwent initial preoperative duplex sonographic scanning to evaluate the carotid lesion. Either digital subtraction cerebral angiography or magnetic resonance angiography was then performed to further define the lesion. Age, sex, risk factors, and indication for operation were recorded in all cases. Preoperative antiplatelet therapy was provided to all patients following identification of a hemodynamically significant stenosis.

The technique of carotid endarterectomy was similar in all cases. Briefly, endarterectomy was performed under general endotracheal anesthesia with continuous intra-arterial pressure monitoring. Intravenous heparin was administered before carotid cross-clamp application to provide a desired activated clotting time (ACT) range of 190 to 250 seconds. Endarterectomy was performed in the standard fashion following routine prophylactic insertion of an intraluminal shunt. Rarely, tacking sutures were used to secure the distal intima. Dacron or BP patch angioplasty was performed to close the arteriotomy using polypropylene suture. Intraoperative ACT was measured following arteriotomy closure. A dry sterile sponge was weighed and placed over the patch material. Suture line bleeding was observed at 3 minutes. If bleeding persisted, the sponge was replaced for an additional minute. The sponge was then removed at 4 minutes to observe suture line bleeding again and then weighed. If bleeding persisted, hemostatic agents were applied. Intraoperative Doppler examination of the internal, external, and common carotid arteries was then performed. A drain was inserted before wound closure and removed on the morning of the first postoperative day. All patients continued antiplatelet therapy postoperatively. Perioperative morbidity, including cervical wound hematoma, transient ischemic attack, and stroke, and perioperative mortality were recorded. Follow-up carotid duplex evaluation was performed in the randomized patients at 1 year after surgery. In addition, to increase our numbers, duplex evaluation was performed in some prerandomization patients who had BP patches placed before the randomization study. Statistical analysis was performed initially using *t* tests, χ^2 analysis, or Fisher exact test, as appropriate. Differences in suture line blood loss (sponge weight) were tested for significance using multiple linear regression to adjust for differences in ACT.

lialization, handles like autologous tissue, and has an excellent host tissue response. However, because of the relatively recent incorporation of available patch mate-

Table 1. Patient Demographics*

Demographic	Bovine Pericardium Group	Dacron Group
Total No. of procedures	51 (54)	44 (46)
Sex		
Male	29 (57)	32 (73)
Female	22 (43)	12 (27)
Mean age (range), y	65.2 (44-89)	66.7 (47-83)
Tobacco	23 (45)	17 (39)
Diabetes	15 (29)	6 (14)
Elevated cholesterol levels	30 (59)	27 (61)
Hypertension	38 (75)	32 (73)
Coronary artery disease	17 (33)	22 (50)

*Data are given as number (percentage) of patients unless otherwise indicated.

Table 2. Surgical Indications

Indication	Bovine Pericardium Group, No. (%)	Dacron Group, No. (%)	<i>P</i> Value
Asymptomatic	24 (47)	20 (45)	.89
Amaurosis fugax	6 (12)	11 (25)	.07
Hemispheric transient ischemic attack	10 (20)	10 (23)	.71
Stroke	11 (22)	3 (7)	.04

rials into the vascular surgeons' armamentarium, there is a paucity of literature demonstrating its efficacy for patch angioplasty following carotid endarterectomy.²⁷ We intend to demonstrate the use of BP as an alternative material for patch angioplasty of the carotid artery following endarterectomy.

RESULTS

Sex, age, and risk factors were similar in the 2 groups (**Table 1**). Indications for operation, including hemodynamically significant asymptomatic carotid stenosis and symptomatic carotid stenosis presenting as amaurosis fugax, transient ischemic attack, or stroke, were also similar in both groups (**Table 2**).

Intraoperative suture line bleeding at 3 minutes was present in 7 (14%) of 51 patients in the BP group and 24 (55%) of 44 patients in the Dacron group ($P < .001$). At 4 minutes, suture line bleeding was present in only 2 (4%) of 51 patients in the BP group and 13 (30%) in the Dacron group ($P = .001$). Net (\pm SEM) sponge weight (total intraoperative suture line bleeding) was 6.25 ± 0.55 g and 16.34 ± 1.85 g in the BP and Dacron groups, respectively ($P < .001$) (**Table 3**). Total suture line bleeding was significantly affected by intraoperative ACT; however, multivariate analysis demonstrated that bleeding was significantly less with BP even after adjusting for differences in ACT ($P < .001$).

The only postoperative cervical wound hematoma occurred in the Dacron group (2%), which did require operative evacuation (**Table 4**). The only neurologic

events occurred in the BP group, including 1 transient ischemic attack (2%) and 1 stroke (2%). The patient sustaining a perioperative stroke made a complete recovery at 1 month without any residual neurologic deficit. There was 1 death following an uneventful endarterectomy and patch angioplasty using Dacron. The patient died at home 1 week after surgery of an unknown cause.

COMMENT

The advantage of patch angioplasty compared with primary closure following carotid endarterectomy has been demonstrated by numerous authors¹⁷⁻²⁷; however, debate continues on which patch material best serves this purpose. Proponents of autologous vein patch angioplasty claim a lower incidence of postoperative thrombosis due to the presence of an intact endothelial surface, inherent suppleness that allows for better approximation to the arterial edge without kinking, immediate sealing of suture holes thereby decreasing the incidence of suture line bleeding and postoperative cervical wound hematoma, resistance to infection, and no additional cost for synthetic material. Despite these advantages, autologous vein patch angioplasty usually requires a separate harvest procedure, increasing the operative time and risk of postoperative morbidity (eg, pain, bleeding, wound infection, delay in ambulation, and hospital stay), which may render the remaining vein unusable for future coronary or peripheral bypass procedures and has a 0% to 4% risk of central vein patch rupture, which usually results in death.²⁸⁻³² Synthetic materials, in contrast, do not require a separate harvest procedure, thereby eliminating longer operative time and associated postoperative morbidity; do not sacrifice a potential conduit for future coronary or peripheral bypass procedures; and do not rupture. However, they may be associated with a higher incidence of postoperative thrombosis and infection, are relatively nonconformable, are associated with increased suture line bleeding and cervical wound hematoma, and, finally, incur the additional cost of the synthetic material. Bovine pericardium exhibits all the advantages of autogenous and synthetic materials without any of the disadvantages, except for the minimal additional cost of the material itself, which is essentially identical to the other synthetic materials currently available. Despite use in cardiac thoracic and neurosurgery for more than 2 decades with excellent results, BP has only recently been introduced for use in arterial reconstruction of the carotid, renal, and peripheral vessels.³³⁻³⁷

In this study, we have demonstrated a statistically significant decrease in intraoperative suture line bleeding using BP even after adjusting for differences in ACT.

Postoperative morbidity in the BP group included 1 (2%) of 51 patients with transient ischemic attacks and 1 (2%) of 51 patients with strokes, which did not reach statistical significance when compared with the Dacron group. This figure agrees with the published stroke risk for carotid endarterectomy. The 1 stroke in the BP group was not the result of carotid thrombosis. Surgical reexploration of the carotid artery disclosed no findings. Finally, 1 death occurred. The patient, a member of the Da-

Table 3. Intraoperative Suture Line Bleeding

	Bovine Pericardium Group	Dacron Group	P Value
Total No. of procedures	51	44	...
Average (\pm SEM) intraoperative ACT, s*	202 \pm 7.3	203 \pm 9.1	.31
Bleeding, No. (%) of patients			
At 3 min	7 (14)	24 (54)	<.001
At 4 min	2 (3.9)	13 (30)	<.001
Net (\pm SEM) sponge weight, g	6.22 \pm 0.55	16.3 \pm 1.8	<.001

*ACT indicates activated clotting time; ellipses, not applicable.

Table 4. Perioperative Morbidity and Mortality*

	Bovine Pericardium Group, No. (%)	Dacron Group, No. (%)	P Value
Total No. of procedures	51	44	...
Cervical wound hematoma	0	1 (2)	.28
Transient ischemic attack	1 (2)	0	.35
Stroke	1 (2)	0	.35
Death	0	1 (2)	.28

*Ellipses indicate not applicable.

cron group who had a history of severe hypertension, died suddenly at home on postoperative day 5. No autopsy was performed. The cause of death was assumed to be secondary to myocardial infarction. In addition, 1 patient in the Dacron group had a significant neck hematoma that required surgical exploration.

We have performed patch angioplasty of the carotid artery following endarterectomy using BP for many years. The most recent 51 cases have been included in this prospective randomized comparison with Dacron. One-year follow-up duplex examinations have been obtained in 73 patients who have had BP patches placed. The incidence of hemodynamically significant recurrent stenosis was defined as 60% or more by duplex sonography. We have identified a significant restenosis in 4 (5%) of 73 patients. This is a favorable restenosis rate when compared with recent publications. None of these patients with restenosis are symptomatic, nor have any progressed to occlusion. No association was identified with age, sex, or risk factors and recurrent carotid stenosis. No aneurysmal degeneration of the BP was identified during the routine 1-year follow-up duplex ultrasound study.

Corresponding author and reprints: James O. Menzoian, MD, Department of Surgery, Boston Medical Center, Room D506, Section of Vascular Surgery, 88 E Newton St, Boston, MA 02118 (e-mail: james.menzoian@bmc.org).

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