Patch angioplasty in carotid endarterectomy. Advantages, concerns, and controversies

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Comments, Opinions, and Reviews

Patch Angioplasty in Carotid Endarterectomy

Advantages, Concerns, and Controversies

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There is much controversy in the literature regarding the precise role of patch angioplasty in carotid endarterectomy. Our report summarizes the theoretical and experimental considerations, including the hemodynamic effects and biologic behavior of the graft, associated with this technique. We present a detailed review of the literature regarding the clinical efficacy of patch angioplasty in carotid endarterectomy, including the early results, the late results, and the incidence and nature of carotid restenosis. We address concerns about the use of patch angioplasty, including the duration of cross-clamping, potential problems with the graft and suture-line disruption, and graft atherogenesis. We conclude that most recent literature indicates that patch angioplasty decreases acute complications (notably carotid occlusion) after carotid endarterectomy and prevents or delays carotid restenosis. As pressure increases to achieve a minimal rate of perioperative morbidity, many surgeons are expected to adopt patch angioplasty in more of their cases. However, in the absence of conclusive results from a prospective randomized study, opinion will continue to be divided regarding the routine versus the selective use of patch grafting in carotid endarterectomy. We present criteria for randomized trials of this technique. (*Stroke* 1989;20:417–422)

Patch angioplasty is the incorporation of a patch graft into the closure of an arteriotomy. Patch angioplasty was popular in the early years of carotid endarterectomy and was believed to contribute to vessel patency.[1,2] With refined vascular techniques, patch angioplasty came to be used more selectively, mostly for the reconstruction of narrow or traumatized arteries.[3–6] More recently there has been renewed interest in the routine use of patch angioplasty to decrease early morbidity and delayed complications of carotid endarterectomy.[7–12]

There is much controversy in the literature regarding the precise role of patch angioplasty in carotid endarterectomy and the impact of this technique on operative outcome. We describe the technique and applications of patch angioplasty, summarize the theoretical and practical considerations associated with its use, and review the literature regarding its clinical efficacy in carotid surgery. Last, we address potential problems and present a general consensus of surgical opinion about the role of patch angioplasty in carotid endarterectomy.

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Theoretical and Experimental Considerations

A detailed presentation of the technical factors of patch angioplasty, the choice of patch material, and its applications in procedures other than simple carotid endarterectomy are beyond the scope of this report. Figure 1 briefly illustrates the technique.

The most striking impact of a patch on the reconstructed vessel is hemodynamic.[7,8,13] Patch angioplasty increases the vessel diameter at the distal end of the arteriotomy from a mean of 4.5 mm to a mean of 7.4 mm. This increase results in a mean threefold increase in the cross-sectional area at the distal end. Furthermore, the patch has the net effects of moving the carotid bulb cephalad and of making the transition in lumen diameter from the common carotid artery (CCA) to the internal carotid artery (ICA) more gradual (Figure 2). The hemodynamic effects of these changes have been estimated to result in a fivefold reduction in shear stress at the origin of the ICA.[13] Such shear stress and the associated changes in peak flow velocity may play roles in early thrombosis and in inducing recurrent atherosclerosis in the wall of the treated artery.[14] An increase in cross-sectional diameter at the critical distal end of the endarterectomy may also lessen the hemodynamic impact of any technical irregularity there. Most experienced surgeons agree that most technical complications of carotid endarterectomy occur at the critical distal end.

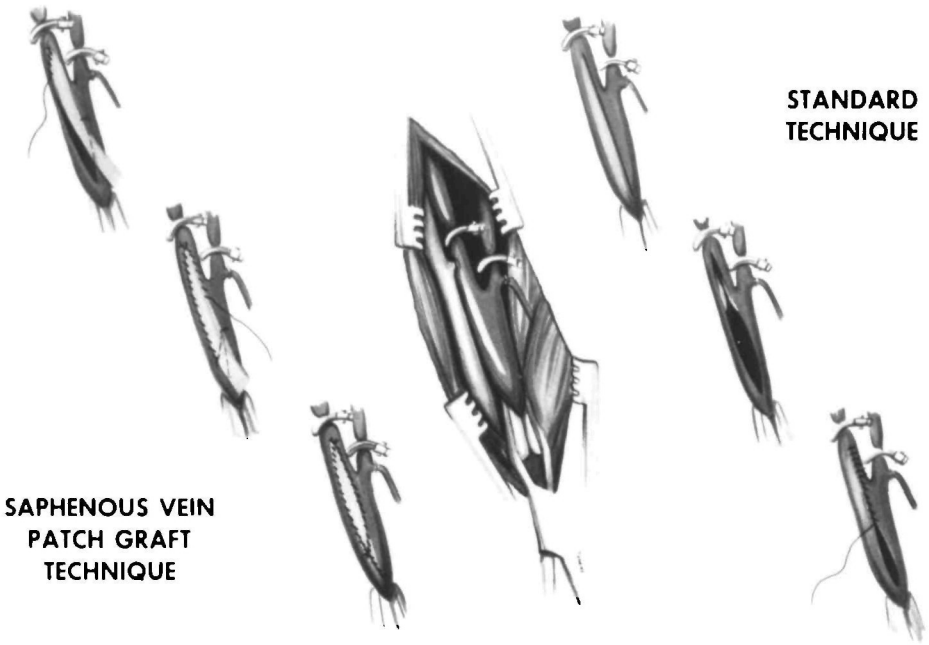

FIGURE 1. *Operative technique of vein patch angioplasty.*

Experimental studies and data from human pathologic specimens have clarified the natural history of vein patch angioplasty (Table 1).[8,14–20] Soon after blood flow is reestablished in the reconstructed vessel, the endothelial surface of the graft "fissures" in multiple areas, possibly as a result of the high-flow state or death of the original endothelial cells. Subsequently, the underlying internal elastic lamellae fragment. These changes are followed by migration of smooth muscle cells from the media to the intima. This myointimal proliferation is later covered by neoendothelium.

Smooth muscle cell proliferation and late neoendothelialization are similar to those occurring in endarterectomized arteries. However, early thrombogenicity and platelet interactions are less prom-

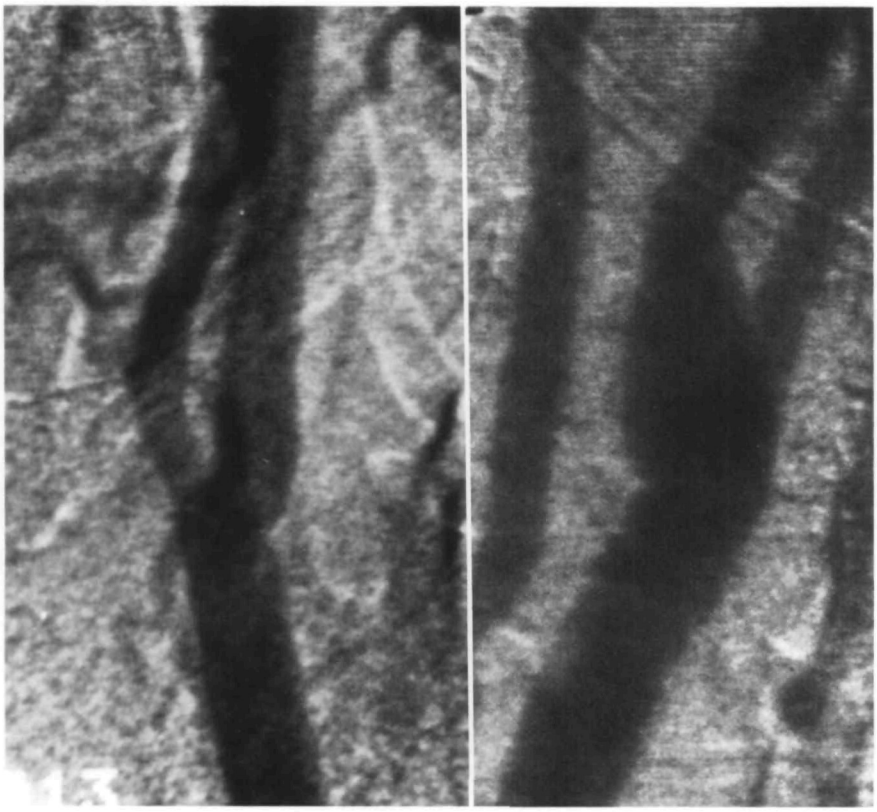

FIGURE 2. *Postoperative digital subtraction angiograms.* Left: *Typical angiogram after conventional carotid endarterectomy.* Right: *Typical angiogram after carotid endarterectomy and saphenous vein angioplasty. Note larger carotid bulb and gradual transition of lumen size beyond bifurcation in patched case.*

TABLE 1. Phases of Healing of Endarterectomized Artery and of Patch Grafts

Phase	Endarterectomized artery	Patch grafts		
		Autologous vein patch	Preclotted Dacron	Processed bovine pericardium
I (hours)	Fibrin polymerization on the exposed media; platelet aggregation*	Fragmentation of endothelial surface and internal elastic lamina	Fibrin polymerization on the graft surface; platelet aggregation*	No reaction
II (days)	Fibromyointimal proliferation	Fibromyointimal proliferation	Fibromyointimal proliferation	No reaction
III (weeks)	Neoendothelialization	Neoendothelialization	Neoendothelialization	No reaction

Precise duration of each phase depends on methodology and model used in investigations; details available in text and respective references.

*Can be altered by platelet inhibition and by anticoagulation.

inent on the graft surface than on the parent artery because the collagen-rich media is never fully denuded or exposed to flowing blood.

The end result of smooth muscle cell proliferation and neoendothelialization is smooth incorporation of the graft into the reconstructed vessel wall.[8] A layer of fibromyointima covers the media of both the graft and the endarterectomized artery and is carpeted by a complete layer of neoendothelium.

The healing mechanisms of preclotted Dacron and polytetrafluoroethylene patches differ slightly[3,5,8] (Table 1). The clotted synthetic surface behaves much like the thin layer of fibrin thrombus covering the media of the endarterectomized artery. Platelet aggregation and dynamic interactions with clotting factors occur on this uniform surface before smooth muscle cells and neoendothelium invade. Other synthetic materials heal differently. It has recently been shown that processed bovine pericardium never witnesses much myofibrous invasion and does not become endothelialized.[21]

Clinical Efficacy of Patch Angioplasty

Patch angioplasty can affect surgical morbidity, including perioperative occlusion and stroke, and can also prevent or delay carotid restenosis and its associated symptoms. Until recently, data regarding these problems was mostly anecdotal. In recent years, several reports have been published comparing conventional carotid endarterectomy with endarterectomy and patch angioplasty. Most of these reports represent consecutive (nonconcurrent) cases of individual surgeons or institutions before and after they adopted patch angioplasty.[7,10,11] One large recent prospective study compared consecutive cases of one surgeon routinely using patch angioplasty with *concurrent* cases of other surgeons on the same service using the technique selectively.[9] We know of three recent randomized prospective studies presented at scientific meetings (Eikenboom at a meeting of the Society of Vascular Surgery in 1987, Claggett at a meeting of the International Society of Cardiovascular Surgery in 1988) or with published methods and entry criteria.[22] The results of these three trials have not been published to date, and we do not know if enough patients were included in each subgroup to ensure the statistical power of any conclusions regarding the various end points of early and late outcome. The results of other, published studies are summarized below.

Early morbidity from carotid endarterectomy comprises systemic and neurologic complications. Many devastating neurologic complications are accompanied by occlusion of the carotid artery. The causes of early morbidity include factors related to patient selection and operative technique.[6,12] One cannot draw any firm conclusions regarding the impact of patch angioplasty unless two sufficiently large groups of cases that are similarly selected and similarly treated in every facet of their care except for patch angioplasty are compared.

In 1984, Little et al[11] compared clinical outcomes and early postoperative intravenous digital subtraction angiograms in 70 consecutive conventional endarterectomies and 50 consecutive endarterectomies with routine saphenous vein patch angioplasty. Early symptomatic ICA occlusion occurred in three and early asymptomatic ICA occlusion occurred in three patients with the conventional operation. There were no occlusions in the routinely patched group ($p=0.04$). The incidence of abnormalities on postoperative angiograms was also significantly greater in the conventional group ($p=0.004$). The occlusions in the conventional group did not occur in the smaller arteries or in the technically more difficult operations. The frequency of occurrence of other systemic and neurologic complications were not significantly different in the two groups.

In 1986, Archie[7] compared his results from 100 consecutive conventional endarterectomies and 100 consecutive routinely patched endarterectomies performed over 30 months. There were no postoperative occlusions, no significant stenoses, no perioperative neurologic symptoms, and no mortality in the routinely patched group. In the conventional group there were nine cases of occlusion or significant postoperative stenosis ($p<0.01$); one cardiac death, one death due to stroke, and two minor ischemic events occurred in the conventional group ($p<0.01$).

In 1987, Katz et al[10] compared their results from 47 consecutive conventional endarterectomies and 42 consecutive endarterectomies with routine vein

patching performed over 30 months. There were two strokes during the postoperative period, both in the conventional group; one stroke was associated with carotid thrombosis. This difference in the frequency of stroke was not statistically significant, nor were there any differences in the frequencies of systemic morbidity or mortality between the two groups.

The study by Hertzer et al[9] published in 1987 compares 483 consecutive conventional endarterectomies with 434 endarterectomies with routine vein patch angioplasty. These cases were not only consecutive but also concurrent (on the same surgical service) over 32 months. One vascular surgeon routinely performed patch angioplasty, while three other vascular surgeons performed conventional endarterectomies, with selective patching in 7% of the cases. Perioperative stroke occurred in 0.7% of the patched cases and in 3.1% of the unpatched cases ($p=0.008$). Postoperative carotid thrombosis occurred in 0.5% of the patched cases and in 3.1% of unpatched cases ($p=0.003$). No symptomatic carotid thrombosis occurred in the patched group. The rate of systemic morbidity or mortality did not differ significantly between the two groups, and operative performance did not differ among the four surgeons. However, this study had an inherent bias against vein patching: unusual or technically difficult cases in which patching was performed by surgeons who do not routinely use the technique were counted as patched cases.

Since none of the above series were randomized, the better results in the patched cases may have been due to factors other than patch angioplasty. However, no comparative study to date suggests that the early results of conventional endarterectomy or selective patching are superior to those obtained with routine patch angioplasty.

Until recently, carotid restenosis was thought to be rare, and carotid endarterectomy was believed to be a very durable operation.[1,2,23] This impression was based on early surgical series with poor and unstructured follow-up and on anecdotal reports of few patients. With the advent of reliable noninvasive diagnostic techniques, the incidence of recurrent stenosis exceeding 50% of lumen diameter has proven to be higher than previously thought. Several recent studies have demonstrated that recurrent stenosis of this magnitude occurs in 10–20% of cases within 2–5 years after surgery.[9,23,24] While the true clinical significance of this restenosis is uncertain, it is sure to have an impact on the long-term benefit of endarterectomy.[9,22,24]

Recurrent stenosis is multifactorial.[8,9,23–25] In the first 24 months aftery surgery, the most common cause of restenosis is myointimal hyperplasia. Subsequently, recurrent atherosclerotic stenosis becomes more prevalent. Either condition can be associated with ischemic symptoms, and either can precipitate thrombosis. Both myointimal hyperplasia and atherosclerosis can be accelerated by vascular risk factors including cigarette smoking. Not all severe recurrent stenosis becomes symptomatic. Similarly, delayed ipsilateral hemispheric symptoms are not all due to carotid restenosis.

Because of the above factors, it can be misleading to compare the relative rates of restenosis and/or late morbidity from different series. However, the available literature allows some preliminary conclusions regarding the impact of patch angioplasty on restenosis.

Patch angioplasty does not afford absolute protection against recurrent carotid stenosis.[9,12,17,24,25] Large centers routinely using patch angioplasty have not eliminated reoperation for this problem. In summarizing the large Mayo Clinic experience with carotid restenosis, Piepgras et al[24] made several interesting observations. In cases with myointimal hyperplasia, the mean interval from initial surgery to reoperation was 10.5 months in patients who had undergone conventional endarterectomy and 23 months in patched patients ($p<0.005$). A similar delay was not demonstrated in cases of recurrent atherosclerosis. Because of the nature of patient referral, no significant conclusions could be reached regarding the actual frequency of carotid restenosis. Restenosis occurred most commonly at the proximal end of the patch in patch angioplasty cases, whereas it most commonly affected the distal end of the arteriotomy in conventional-closure cases.

Deriu et al[8] and Imparato and Weinstein[17] reviewed their personal experiences and concluded that carotid restenosis was infrequent in their patients because of patch angioplasty; their reports, however, are limited by the lack of suitable controls. Katz et al[10] compared the incidence of restenosis in the first 2 years after carotid endarterectomy in 47 consecutive unpatched cases and in 42 consecutive cases with vein patch angioplasty from the same surgical service. Symptomatic or severe (>50%) restenosis occurred in 19.1% of the unpatched group and in 2.4% of the patched group ($p<0.05$). Curley et al[25] found no significant difference in the incidence of restenosis between patched and unpatched cases followed for 2 years, but the number of patients in each group was very small (22 patched, 23 unpatched), making statistical conclusions about this lack of correlation questionable.

Hertzer et al[9] examined the incidence of restenosis in more than 900 cases followed with noninvasive techniques. The 3-year incidence of recurrent stenosis was three times as high in unpatched patients ($p=0.007$). Seven unpatched patients and three patched patients required reoperation for recurrent stenosis during the 3-year follow-up.

No report in the literature suggests or demonstrates superior delayed results with conventional endarterectomy or selective patching compared with routine patch angioplasty.

Concerns Regarding Patch Angioplasty

Despite its demonstrated clinical efficacy and recent shifts of many surgeons to patch angioplasty,

the weight of opinion in the surgical community continues to be against the *routine* use of patch angioplasty in carotid endarterectomy. Several reputable surgeons have published large series demonstrating excellent operative results without patch angioplasty and have attributed their success to other technical factors.[3,4,6] While it is difficult to place these results in proper perspective without suitable controls, such opinions continue to influence the surgical community at large.

In addition, concerns have been raised regarding the increased cross-clamp time required for patch angioplasty, the dangers of graft or suture-line disruption, and the graft's possible contribution to late atherogenesis. We discuss these issues sequentially.

Clearly, patch angioplasty increases the carotid cross-clamp time required for endarterectomy. In the series of Little et al,[11] the time required was approximately 15 minutes longer in the patched group than in the conventional group. Deriu et al[8] reported carotid cross-clamp times of 30–45 minutes in the patched group and 12–15 minutes in the conventional group. In both series, intraoperative electroencephalographic monitoring was used, with selective shunting for electroencephalographic changes suggestive of ischemia.

These reports and other studies (see "Clinical Efficacy" section) show no evidence that lengthened cross-clamp time results in increased perioperative morbidity. This lack of evidence supports the increasingly frequent opinion of surgeons that perioperative neurologic complications are less related to cross-clamp time than to meticulous surgical technique, provided there is reliable intraoperative monitoring and cerebral protection.[3,4,8,9,11]

Patch angioplasty increases the length of the suture line, thus increasing the theoretical risk of suture-line disruption. In addition, the technique introduces the risk of early or delayed graft breakdown, leading to hemorrhagic complications or aneurysm formation.[26–29] Infection in a synthetic graft may aggravate this problem.

The risks of the above complications are very low and possibly protracted; large, well-structured studies are required to demonstrate or rule out an effect of patch angioplasty. Perioperative hemorrhagic complications were identical in the patched and unpatched groups in the series of Little et al,[11] Archie,[7] and Katz et al.[10]

Katz et al[10] refer to a previous experience with three vein patch disruptions (not included in their report) attributed by the authors to their use of vein from just above the medial malleolus rather than proximal saphenous vein. Hertzer et al[9] examined 917 cases: three false aneurysms developed over 3 years in the patched cases, and none developed in the unpatched group; the false aneurysms were repaired without morbidity. That study illustrates that many patients are required to uncover the slightest trend, which may or may not be statistically significant.

The risk of delayed aneurysm formation is even more difficult to characterize. Infection, suture-line disruption, and patching have all been anecdotally implicated as etiologic factors.[26–28] Thompson et al[5] reported seven delayed aneurysms in their series of 1,140 carotid endarterectomies; all seven had been subjected to Dacron patching. In 1986, Branch and Davis[28] reviewed the English-language literature and identified 57 reported cases of this complication; 40 had undergone patch angioplasty. Branch and Davis[28] analyzed 30 cases with sufficient data for determining incidence figures, and they calculated a 0.25% incidence of aneurysm formation after conventional carotid endarterectomy and a 0.33% incidence after patch angioplasty; the numbers were too small for meaningful statistical analysis. Infection accounted for half of the aneurysms in the patched and unpatched groups.

In animal models, venous structures subjected to arterial pressure develop an accelerated form of atherosclerosis.[13,15,20] This has also been noted in saphenous veins used for coronary artery bypass procedures. Whether the same process occurs in arterioplastic patches remains to be proven. In the Mayo Clinic report on carotid restenosis, atherosclerotic recurrence was neither more prevalent nor more rapid in patched cases.[24]

Conclusions

Surgeons uniformly agree that patch angioplasty provides a unique advantage in the reconstruction of narrow or traumatized carotid arteries. However, debate continues regarding the routine use of this technique in carotid endarterectomy. Recent literature supports the contention that patch angioplasty decreases acute complications (notably carotid occlusion) after carotid endarterectomy and prevents or delays recurrent carotid stenosis. The benefit may be due to hemodynamic effects of the patch, to the biologic behavior of the graft, or to unknown factors. Specific subgroups of patients more likely to derive benefit from patch angioplasty have not been identified. Concerns regarding cross-clamp time, graft or suture-line disruption, and delayed graft atherogenesis have yet to be substantiated.

With increasing pressure to lower perioperative morbidity, more surgeons are expected to use patch angioplasty in an increasing number of patients. However, in the absence of conclusive results of prospective randomized studies, surgical opinion will continue to be divided regarding the routine versus selective use of patch grafting in carotid endarterectomy. Randomized trials designed to address this issue should be stratified, controlling for patient characteristics, angiographic features, and extent of disease. Each subgroup should contain enough patients to support any negative results with adequate statistical power (no easy task in view of the low frequency and protracted nature of many end points). Trial designs should include prospective criteria for "selective patching" in

patients randomized into the unpatched group and statistically valid methods of dealing with these cases. Finally, end points should include as a minimum early and late clinical and angiographic (or echographic) outcomes.

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