Hypothesis: Endovascular interventions have revolutionized the contemporary treatment of peripheral vascular occlusive disease. Traditional management of supra-aortic trunk disease has employed surgical extra-anatomic bypass via a cervical approach or median sternotomy. Endoluminal therapy may be a less morbid alternative.

Design and Setting: A retrospective review of procedures performed by vascular surgeons in an operating room angiosuite at a single university-based, tertiary referral center.

Patients: Eighteen consecutive patients with 20 brachiocephalic-origin stenoses.

Interventions: From December 2001 through September 2005, 20 brachiocephalic-origin stenoses were treated endoluminally with balloon-expandable stents. Treated vessels were innominate (n=8), common carotid (n=9), and subclavian (n=3). The target lesion was accessed by one of the following methods: antegrade via the femoral artery (n=5), retrograde through the brachial artery (n=1), or via a retrograde cut-down on the common carotid artery (n=14). Cerebral protection was achieved with either a distal embolic filter device or with open surgical occlusion of the distal common carotid artery.

Main Outcome Measures: We report immediate and midterm outcomes of all aortic arch vessel stenting procedures with mean follow-up of 12 months.

Results: Mean age was 68 years (6 men and 12 women) and overall mean stenosis was 85%. Preprocedural symptoms including stroke, transient ischemic attack, arm fatigue, digital ischemia, and angina were present in 16 of 20 cases (80%). The 4 asymptomatic patients all had more than 90% stenosis on angiography. At 30-day follow-up, there were no deaths, myocardial infarctions, or strokes. During follow-up, there were no cases of restenosis.

Conclusion: Endoluminal arterial stenting of brachiocephalic arch vessels may be a viable alternative to traditional open bypass in cases of focal stenotic disease.

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Despite early success with PTA and stenting, the risk of atheroembolization remained a concern. In 1996, Queral and Criado demonstrated the safety and efficacy of a hybrid, open, and endovascular technique with surgical exposure of the common carotid artery with distal clamping to prevent distal embolization prior to the retrograde deployment of Palmaz stents to treat lesions of the SATs. We recognize the importance of protecting against distal atheroembolization and report the midterm results of our series of aortic arch vessel stenting with distal embolic protection using either open surgical distal occlusion or an endoluminal embolic protection device at a single institution in an operating room angiosuite.

METHODS

From December 2001 through September 2005, 20 brachioccephalic vessel lesions were treated in 18 patients at Northwestern Memorial Hospital, Chicago, Ill. This is a single-center retrospective review of those 20 cases. The target lesions included 8 innominate, 9 common carotid, and 3 subclavian artery atherosclerotic stenoses. These procedures were performed under general anesthesia (n = 13), monitored anesthesia care with local anesthetic and intravenous sedation (n = 5), or local anesthetic alone (n = 2) in a fully functional operating room angiosuite with a fixed, ceiling-mounted fluoroscopic imaging unit (Philips Medical Systems, Bothell, Wash).

Access to the SAT lesion was achieved in a retrograde fashion via a brachial artery puncture (n = 1) or a common carotid artery cutdown (n = 14), and in an antegrade fashion via a common femoral artery puncture (n = 5). In all but 4 cases, cerebral protection was achieved by either open surgical distal common carotid artery clamping (n = 14) or use of an embolic protection device. The 4 cases in which cerebral protection was not used included all 3 subclavian artery procedures accessed through common femoral artery punctures and 1 innominate artery stenting procedure accessed via a right brachial artery puncture.

All patients underwent preoperative physical examinations with bilateral arm pressure measurements and had duplex scanning performed in our institution’s vascular laboratory accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories. As part of the preoperative assessment of patients, either a conventional arteriography or magnetic resonance angiography was performed to confirm the lesions suggested by physical examination or duplex scanning. In the majority of cases, patients were given clopidogrel (75 mg) and aspirin (325 mg daily) for at least 5 days before the intended procedure.

After having gained access and placing a 6F sheath intrarally, intraoperative arteriography was used to confirm the location of the lesions (Figure 1). Prior to establishing the aforementioned methods of cerebral protection and prior to crossing the lesions with a 0.035-in guidewire, standard doses of intravenous heparin were given to achieve an activated clotting time of 250 seconds or longer. In 1 case of a greater than 89% stenosis present in the common carotid artery, preangioplasty ballooning was required to cross the lesion with the stent. In all other cases, the SAT lesions were treated with primary stenting using balloon-expandable stents. If used, the commercially available embolic protection devices were recovered after completion angiograms were obtained for evidence of vasospasm, dissection, or residual stenosis (Figure 2). If residual stenosis was suggested by the completion angiogram, postprocedure angioplasty was performed with care taken to maintain the balloon within the confines of the stent. In cases where a distal clamp occlusion was used as cerebral protection, the stagnant column of blood surrounding the sheath was aspirated and the clamp was removed to back-bleed the vessel prior to establishing antegrade flow.

Three patients underwent combined procedures consisting of conventional carotid endarterectomy and concomitant retrograde stenting of SAT lesions. Two patients were noted to have tandem lesions at the origin of the left carotid artery and the carotid bifurcation on preoperative assessment, and 1 patient had a lesion at the origin of the innominate artery in
conjunction with a lesion in the right internal carotid artery. The stenting procedures were performed as described previously and followed by standard carotid endarterectomy for the treatment of carotid bifurcation lesions.

Duplex scanning and physical examinations with arm pressure measurements were obtained postoperatively, and at 6-month intervals thereafter. Computed tomography angiograms were obtained to assess for in-stent stenosis if either physical examination or duplex scanning findings was abnormal. Mean follow-up for this patient population is 12 months. The design of this study was approved by and compliant with the standards set forth by the institutional review board.

RESULTS

Eighteen patients (6 men [33%] and 12 women [67%]) with a mean age of 68 years underwent aortic arch vessel stenting. One patient underwent stenting of the innominate, left common carotid, and left subclavian arteries at 3 separate settings, accounting for a total of 20 SAT stenting procedures. The overall mean stenosis treatment rate was 85%, which was determined by preoperative angiography and confirmed in all cases by intraoperative angiogram at the time of procedure. Sixteen (80%) of the 20 procedures were performed for symptomatic disease. Symptoms included transient ischemic attack (n=8), stroke (n=3), arm fatigue (n=3), digital ischemia (n=1), and angina (n=1) in a patient with a prior left internal mammary-to-coronary artery bypass graft. The remaining 4 procedures were performed in patients with asymptomatic disease but angiographic evidence of at least 90% stenosis.

Mean length of hospital stay was 1.2 days. There were no perioperative procedure-related complications and at 30-day follow-up, there were no deaths, myocardial infarctions, or strokes. Throughout follow-up, there have been no cases of restenosis detected by routine duplex surveillance and all patients have remained symptom free. Additionally throughout follow-up, there have been no late target vessel–related complications or deaths.

COMMENT

The treatment of atherosclerotic SAT vessel stenoses has experienced a variety of approaches since the original surgical repair was reported by Shimizu and Sano in 1951.1 Largely influenced by the desire to reduce the mortality rate associated with transthoracic repair of these lesions, noted to be as high as 22% in 1 series, Dietrich et al1 and later Crawford et al1 demonstrated that mortality rates could be reduced dramatically to 5.6% with extra-anatomic cervical repair of aortic arch vessel lesions. In a report describing a 16-year experience, Berguer et al1 demonstrated that symptomatic and asymptomatic lesions of SATs could be addressed by cervical reconstruction with acceptable death (0.5%) and stroke (3.8%) rates. Additionally, they reported a 5- and 10-year primary patency rate of 91% and 82%, respectively—excellent results and clearly the standard by which other treatment approaches are to be compared.

Naturally, following reports of the successful treatment of peripheral, renal, and coronary artery atherosclerotic lesions by PTA in the 1970s20,21 several investigators applied these same techniques to lesions of the brachiocephalic vessels and published their results nearly a decade later.9,10 While these interventions were well tolerated by most patients and demonstrated acceptable perioperative efficacy and safety, long-term patency and freedom from reintervention were found to be inferior to the more invasive transthoracic and extra-anatomic reconstructions. Stenting was subsequently introduced to address these issues and theoretically reduce the risk of atheroembolization.

With the encouraging results seen by the use of embolic protection devices in the treatment of isolated carotid artery stenoses, we are further reminded of the importance of providing cerebral protection in the setting of extracranial cervical vessel manipulation. Queral and Criado18 recognized the importance of protecting against distal atheroembolization and described their technique of distal clamp occlusion in 1996. We applied their method to our patients undergoing retrograde stenting procedures via open cut-down on the common carotid artery and we, likewise, had no patients suffering perioperative strokes. In this series, there were 4 patients in whom embolic protection was not used either because it was not possible or was not deemed necessary. There was 1 patient who underwent treatment of an innominate lesion via a brachial approach. This patient had femoral artery occlusive disease that prevented access to the lesion via a femoral approach. The remaining 3 patients were those who were treated for lesions of the left subclavian artery. While distal embolization to the posterior circulation through the vertebral artery is theoretically possible, collateral flow was deemed adequate from preoperative angiography.

Prior studies have reported excellent results using endovascular techniques for the treatment of focal brachiocephalic vessel lesions. Unlike these studies by Sullivan et al14 and Queral and Criado,18 where 76% and 46% of the lesions treated, respectively, were for focal stenoses of the left subclavian artery, only 15% of the patients treated in our series required intervention for lesions of the left subclavian artery. Rarely do lesions of the left subclavian artery warrant treatment because of profound clinical symptoms. One of our cases, a patient who had previously undergone a left internal mammary-to-coronary artery bypass and subsequently developed angina from a steal phenomenon, required treatment of a subclavian lesion. In this setting and when significant arm fatigue or digital ischemia can be attributed to atherosclerotic lesions of the left subclavian artery, intervention is needed but unlike other reports, these conditions were the minority in our experience.

Asymptomatic lesions of the SATs infrequently warrant intervention. In this series, we treated 4 lesions in patients who were asymptomatic, but all 4 lesions were shown to be high-grade stenoses (>90%) angiographically. Applying established criteria for the treatment of carotid disease, we felt that these lesions needed to be addressed. Two of these lesions were found in 1 patient undergoing treatment for symptomatic left subclavian artery stenosis. The innominate and left carotid artery lesions were subsequently treated in separate settings. The remaining 2 lesions involved the left carotid artery or-
gin and were treated at the same time as endarterectomy of left carotid artery bifurcation lesions. While guidelines for the treatment of asymptomatic lesions of the SATs have yet to be established, it is hard to ignore tandem carotid artery lesions when they are demonstrated by angiography to be high-grade.

The endovascular approach has many theoretical advantages over open surgical repair including the ability to perform such procedures without the need for general anesthesia, quicker recovery times, shorter length of hospital stay, and lower costs—I study reported a mean savings of $8787 per procedure. One argument used to explain why transhilarcarotid endarterectomy or bypass demonstrated slightly superior long-term patency compared with extra-anatomic cervical reconstruction was the fact that aortic inflow is preserved with the former approach. The endovascular approach has the same inherent advantage. Furthermore, diffuse atherosclerotic lesions are commonplace to this patient population and many are at increased risk for suffering cardiac events in the perioperative period. High-risk patients such as these and others with significant comorbidities, previous cervical operations, or prior cervical irradiation are likely to benefit from an endovascular approach to aortic arch vessel disease. During this same time period, we treated an additional 10 patients with disease of the SATs by means of either a transthoracic or cervical approach.}

Open revascularization was used in this patient population because preoperative imaging demonstrated these lesions to be complete occlusions. In the setting of complete occlusions, we advocate open reconstruction rather than an endovascular approach, but with experience and technological advances, perhaps complete occlusions could be treated with endoluminal techniques as well.

While open surgical bypass provides a durable solution for addressing SAT vessel disease in suitable patients, endoluminal stenting of the brachiocephalic arch vessels is a viable alternative in cases of focal stenotic disease because it has an excellent functional outcome, safety, and midterm results.

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DISCUSSION

Bruce L. Gewertz, MD, Chicago, Ill: I enjoyed this paper and the fine presentation. The results are excellent with no recurrences and no complications of treatment. Hard to argue with that. I have several comments and 3 questions for the authors.

REFERENCES

First, it must be acknowledged that these are actually quite short-term results with a mean follow-up of only 12 months. I would certainly agree that the absence of symptoms during this time period is encouraging. That said, the principal concern regarding angioplasty with or without stent placement is recurrence. The relatively short interval does not answer that critical durability question.

It is also important to note that most of these patients did undergo surgery. Fourteen of the 18 patients had operative exposure of their carotid arteries; 3 patients had concurrent carotid endarterectomies.

I would ask the authors to address these issues: Understanding that this is a retrospective review, what was the volume of similar cases handled with open operations during that same time period? In other words, what are the considerations that prompt the authors to use angioplasty and what would be the indications for a direct or extra-anatomic open surgical approach?

Noting that carotid stenting is associated with a higher incidence of complications in patients 80 years old or greater, do they feel that other brachiocephalic angioplasties such as those described today should be avoided in octogenarians? This is particularly important since such patients with comorbidities would presumably be at greater risk for general anesthesia and surgical procedures.

Finally, we routinely use Plavix or other antiplatelet agents to retard the development of intimal hyperplasia after angioplasty. Do the authors use antiplatelet therapy and for how long after these procedures?

This is a very helpful report reflecting the real change in treatment of symptomatic lesions. Additional work is needed since our understanding of the more plentiful asymptomatic plaques remains incomplete. I also note in this paper the predominance of women, which contrasts with the male-dominant carotid series that are generally reported.

I fully concur with the paper’s discussion which concludes that “endoluminal stenting is a viable alternative to traditional open bypass.” I may not yet agree with the title, which suggests that bypasses are obsolete. It is my guess that long-term outcomes coupled with further refinement in indications will lead to a place for both operative and endovascular therapies in the treatment of diverse brachiocephalic lesions.

Dr. Peterson: During a similar time period, we performed, I believe, 6 open operations. The decision-making process that went along with deciding whether patients were candidates for endoluminal intervention or open repair—basically if patients were good risk patients and the stenoses were focal origin stenosis and not diffuse, they were candidates for the endoluminal technique. Additionally, heavily calcified lesions are to be avoided because of the point exactly that you made regarding late restenosis or the durability of these procedures.

Also, in the setting of complete occlusions, I know some groups have tried to recanalize these and have treated them with angioplasty and stenting procedures but we don’t believe that the long-term durability of using endovascular techniques in the setting of complete occlusions is proven. But when patients are good risks, certainly the mainstay of treatment is surgical bypass or extra-anatomic bypass. And then patients, much like in our internal carotid artery experience, that most likely will benefit the most from endoluminal techniques are high-risk patients with severe comorbidities or significant coronary artery disease or valvular disease.

As for the treatment of octogenarians, we certainly don’t let chronological age discriminate against intervening in the endovascular manner on these patients. It is more their physiological age. And again, if the patient is a good risk from a physiological standpoint, we will certainly consider them for intervention.

As for our antiplatelet regimen, we typically start patients on Plavix before surgery. I know there might be some slight concern for bleeding postoperatively given the fact that we do have a cervical incision in the majority of these cases, but we haven’t run into any problems with hematoma formation postoperatively.

We typically start patients on Plavix, 75 mg, for at least 5 days prior to the surgery. And if we are unable to have them start 5 days preoperatively, we load them with 300 mg of Plavix on the morning of the operation and typically continue these patients on aspirin and Plavix.

Laurens R. Pickard, MD, Houston, Tex: I have a question about the maneuver of clamping the carotid artery for protection in that group of patients. If the concept is to control debris, do you open and flush the vessel?

Dr. Peterson: Yes, we do. We allow the vessel to back-bleed after completion of the angioplasty and stenting procedure to flush out any debris that might have been dislodged from that.