Peripheral Interventions

Stenting for Occlusion of the Subclavian Arteries

Technical Aspects and Follow-up Results

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We report the results of stenting in 17 patients who underwent treatment for total occlusions in the subclavian arteries between July 1991 and December 1995. Fourteen of the lesions were located in the left side; 15 patients had a subclavian steal syndrome. The indications for treatment were vertebrobasilar insufficiency (n=7); arm claudication (n=5); vertebrobasilar insufficiency and upper-limb ischemia (n=3); protection of a left internal mammary artery coronary bypass (n=1); and an isolated subclavian steal syndrome (n=1).

A total of 23 stents were implanted in 17 patients; in 1 patient, 2 stents migrated during deployment, resulting in a 94% procedural success rate. One case of axillary thrombosis was successfully treated with local thrombolysis and balloon angioplasty. There were no postprocedural neurologic complications or deaths. Follow-up over a mean duration of 19.4 months (range, 4 to 56 months) revealed 1 asymptomatic restenosis at 5 months in a patient with 3 stents. Life-table analysis showed an 81% cumulative patency rate at 6 months.

We conclude that stenting for occlusion of the subclavian arteries appears feasible and safe; however, further evaluation in a larger group of patients is needed to confirm these results. ***(Tex Heart Inst J 1997;24:23-7)***

The 1st subclavian artery angioplasty was reported in 1980 by Bachman and Kim.[1] Since then, percutaneous treatment of subclavian artery stenosis has been in frequent use despite a wide variance in procedural success and initial concern over the potential for thromboembolic complications and restenosis.[2-7] More recently, stenting has been used successfully to improve luminal diameter and restore flow in occluded arteries, and its value in the reduction of thromboembolization and restenosis in the iliac and renal arteries has been documented.[8-10]

Early experience with stenting for subclavian stenosis[11-13] indicates that percutaneous management of subclavian occlusions may offer significant advantages over classical surgical intervention, including the avoidance of a cervical incision and general anesthesia, shorter duration of induced occlusion, improved access to some lesions, and reductions in hospital stay and the need for postoperative surveillance. Furthermore, the use of stents may be able to improve the rather poor results seen thus far with balloon dilation in subclavian occlusions.[3]

To examine whether the use of stents can enhance the outcome of percutaneous treatment for subclavian occlusions, we reviewed our angioplasty experience with this disease over the past 4.5 years.

Key words: *Angioplasty, balloon; arterial occlusive diseases/therapy; atherosclerosis/therapy; blood vessel prosthesis; brachiocephalic trunk; stents; subclavian artery; treatment outcome; vascular patency*

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Patients and Methods

Patient Characteristics

From July 1991 through December 1995, 17 patients (10 men; mean age, 64 years; range, 34 to 79 years) were selected in a nonrandomized, consecutive order to participate in a protocol, approved by our Institutional Review Board, to evaluate the use of stents for treatment of occluded subclavian arteries. All patients underwent routine examination, including duplex scanning and arteriography. The risk factors in this population included hypercholesterolemia (n=8), diabetes (n=1), hypertension (n=11), and smoking (n=12). Ischemic heart disease was present in 11 patients (65%); 5 patients had undergone a previous coronary artery bypass, and 3 of these procedures included the use of a left internal mammary artery.

Percutaneous coronary angioplasty was performed in 2 patients. Disease in the other 4 patients was controlled by medical treatment. Symptomatic peripheral arterial occlusive disease affected 9 patients (52%).

Atherosclerotic occlusions of the subclavian artery were present in the prevertebral segments of 16 patients, in the postvertebral segment in 1, and in the left subclavian artery in 14. Fifteen patients had retrograde flow in the ipsilateral vertebral artery. This artery was occluded in the 2 remaining patients.

The indications for treatment were as follows: vertebrobasilar insufficiency (symptoms included dizziness, visual disturbance, slight headaches, and dysarthria) in 7 patients (41.2%); arm claudication in 5 (29.4%); vertebrobasilar insufficiency and upper-extremity ischemia in 3 (17.6%); protection of a left internal mammary artery coronary bypass in 1 (5.9%); and an isolated subclavian steal syndrome in 1 (5.9%).

Techniques

The procedures were performed in an operative suite under either general (n=14) or local anesthesia (n=3), depending on the method agreed upon by the patient and the anesthesiologist. In every case, bilateral transradial blood pressure monitoring was used, and pressure gradients were recorded at the affected site.

A brachial approach was used in 16 patients and a femoral approach was used in the remaining 1. A 7-F sheath was introduced percutaneously, and heparin was administered to maintain the activated coagulation time (ACT) above 250 seconds. The lesion was crossed with an 80-cm, 0.035-inch, angled hydrophilic-coated guidewire (Glidewire® guidewire, Medi-tech®/Boston Scientific Corporation; Natick, Mass); a 5-F angiographic straight catheter (Medi-tech®/Boston Scientific Corporation) was advanced over the guidewire to allow safe and easy access through the occlusion. In 1 case, the low profile angioplasty catheter could not pass the occlusion, and atherectomy (Rotablator®, Heart Technology, Inc.; Bellevue, Wash) was used to recanalize the lesion.

Fluoroscopic guidance, contrast injection, and roadmapping allowed accurate placement of the angioplasty balloon (size range, 4 to 9 mm) for predilation. In general, the diameter of the predilation balloon was 1 size smaller than that of the stent delivery balloon. Selection of stent size was based on the diameter of the adjacent normal vessel and the length of the lesion. PALMAZ™ Balloon-Expandable stents (Johnson & Johnson Cordis Corp. affiliate; Miami Lakes, Fla) were preferred (n=19); however, 1 Strecker™ stent (Medi-tech®/Boston Scientific Corporation) was used at the beginning of our experience, and the WALLSTENT® Endoprosthesis (n=3) by Schneider (USA), Inc, Minneapolis, Minn, was used in long lesions where longitudinal flexibility was needed (e.g., curved vessels and locations affected by arm movement).

After stent deployment, an angiographic control study was performed and the pressure gradient was recorded. Intravascular ultrasound imaging was used in 3 cases. After completion of the procedure, patients were transferred to the intensive care unit and monitored. The sheath was withdrawn when the ACT was below 150 seconds. Patients were usually discharged the day after the procedure and were placed on antiplatelet therapy (aspirin and dipyridamole).

Definitions, Follow-up Methods, and Statistical Analysis

Immediate technical success was defined as adequate stent expansion at the appropriate site, satisfactory angiographic results (no residual stenosis, dissection, or extravasation of the contrast material), and the absence of a pressure gradient between the 2 radial arteries. Patients were evaluated at 1, 6, and 12 months, at which time an interview, clinical examination, blood pressure measurement in both arms, and duplex scanning were performed. Patency of the stented segment was demonstrated by means of duplex scanning, arteriography, or both. Cumulative patency rates were calculated by the life-table method as defined by the Subcommittee on Reporting Standards for Cerebrovascular Disease, Ad Hoc Committee on Reporting Standards of the Society for Vascular Surgery/North American Chapter, International Society for Cardiovascular Surgery.[14] All data were analyzed by VascuBase™ statistical software (Consensus Medical Systems, Inc.; Seattle, Wash).

Results

Stent placement was successful in 16 of 17 patients (94% procedural success). In the 17th patient, 2 consecutive PALMAZ stents migrated during delivery; these were deployed in the postvertebral segment of the subclavian artery and in the brachial artery; the subclavian lesion was then overdilated.

Twenty-one stents (17 PALMAZ, 3 WALLSTENT, 1 Strecker) were implanted successfully in the remaining 16 patients. Single stents were placed in 12 patients; 3 patients received 2 stents each, and 1 patient received 3 stents. In 14 cases, stents were deployed in the 1st segment of the subclavian artery (Fig. 1). One lengthy occlusion in the postvertebral segment required implantation of 2 WALLSTENTS (Fig. 2). In another patient, a PALMAZ stent was placed across the ostium of the vertebral artery.

One case of axillary artery thrombosis occurred and was treated with local thrombolysis and balloon angioplasty; immediate satisfactory hemodynamic

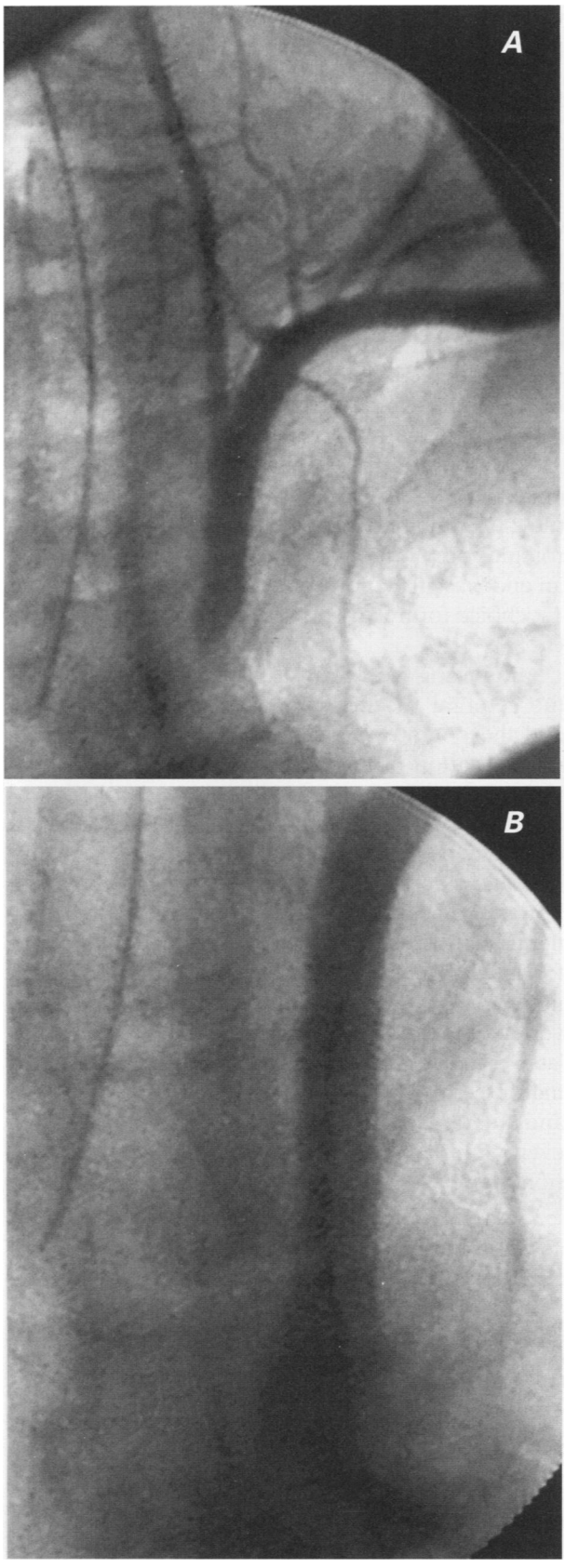

Fig. 1 *A) Angiogram showing a typical short occlusion at the origin of the left subclavian artery. B) Stent placement in the proximal left subclavian artery permitted restoration of vessel patency.*

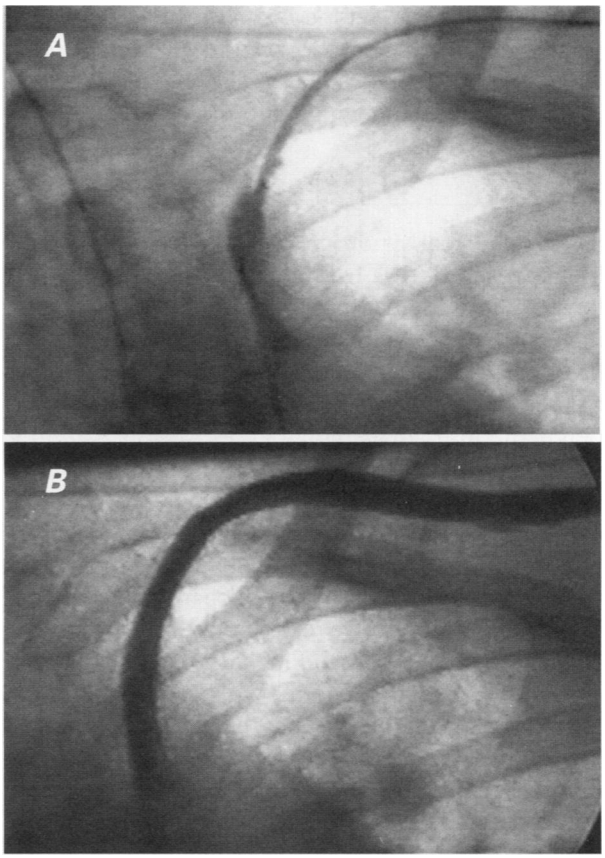

Fig. 2 *A lengthy left subclavian occlusion (A) required implantation of 2 WALLSTENTS for satisfactory treatment outcome (B).*

and angiographic results were achieved. There were no neurologic complications or deaths. The subclavian lesions of all 17 patients were successfully recanalized with complete resolution of the blood pressure gradient and preoperative symptoms.

Follow-up ranged from 4 to 56 months (mean, 19.4 months). Three patients with 4 PALMAZ stents were lost to follow-up, and 1 patient with a PALMAZ stent died of an unknown cause 11 months after placement. The patient with 3 PALMAZ stents presented 5 months after stent placement with asymptomatic restenosis but conservation of antegrade flow in the vertebral artery. Balloon angioplasty was performed with good results; 5 months later the patient remained asymptomatic with no stenosis identified on duplex scan. All the WALLSTENTS and the Strecker stent were patent when they were last examined.

The patient with the overdilated lesion had a palpable ipsilateral radial pulse and no pressure gradient between the 2 arms at 45 months. The subclavian artery was patent without evidence of restenosis, and antegrade flow in the vertebral artery was demonstrated by duplex scan. Follow-up at 56 months in the patient with a stent across the vertebral os-

tium revealed no symptoms or restenosis in the stented area. Antegrade flow was present in the vertebral artery. Life-table analysis shows an 81% cumulative primary patency rate at 6 months (Table I).

Discussion

Subclavian steal syndrome was 1st described in the literature in 1961.[15] In the 25 years that have followed, the benefit of prompt diagnosis and treatment of patients with occlusive subclavian disease has been well established.[16-19] The development of balloon angioplasty and stenting made possible the percutaneous management of these lesions, offering substantial advantages over classical intervention. Stenting has been used successfully to correct arterial obliterative lesions in the iliac arteries and has yielded lower restenosis rates than those achieved with balloon angioplasty.[8] Palmaz and colleagues,[10] in a multicenter study, reported treatment success rates to be higher in patients with recanalized iliac occlusions than in patients with stenotic lesions. Those authors suggested that the reduced endothelial surface area in occluded arteries may lower the potential for intimal hyperplasia and restenosis.

Although the immediate technical success of stent placement in this series was 94%, percutaneous techniques allowed restoration of patency and flow in all of the lesions approached. We preferred the brachial approach because of its proximity to the left subclavian orifice and its potential to avoid access site complications in the groin. We succeeded in crossing lesions with the hydrophilic-coated guidewire (using a 5-F angiographic catheter over the guidewire as needed), which was maneuvered cautiously to avoid dissection or arterial wall perforation. Our use of the Rotablator had previously been limited to the lower extremities; however, we used it successfully in this series to treat a heavily calcified subclavian lesion before deploying the stent. An excellent immediate result was achieved, and the patient remained asymptomatic without recurrent stenosis 56 months after the procedure. This is an isolated case, so no conclusions can be drawn from this single experience.

Transthoracic and extrathoracic revascularization procedures carry a 4% to 11% morbidity rate and a 0 to 5% mortality rate.[19-21] Potential complications include thoracic duct fistula, Horner's syndrome, supraclavicular nerve damage, and decompensation of pre-existing ischemic cardiomyopathy or cerebrovascular atherosclerotic occlusive disease. Given the preoperative condition of the patients in our study, the morbidity and mortality rates might well have been higher with conventional surgical treatment. Although more than 50% of the patients had ischemic heart disease, lesions of the cerebral artery, or the 2 in combination, there were no cardiac or neurologic complications. Our experience suggests that an endovascular approach may be appropriate as the 1st choice for treatment of subclavian occlusive disease.

Minimizing the risk of stroke during restoration of the cerebral vasculature is a major consideration, and the potential for thromboembolization during recanalization of an occluded prevertebral subclavian is always a concern. Sharma and colleagues[2] have reported that patients with antegrade vertebral flow may be particularly vulnerable to cerebral embolization during the procedure. As early as 1980, however, Bachman and Kim[1] recognized that in patients with subclavian steal syndrome, angioplasty for subclavian artery stenosis was associated with a notable delay in the re-establishment of antegrade vertebral flow. This unexplained phenomenon was later confirmed by continuous ultrasound monitoring of the ipsilateral vertebral artery before, during, and after angioplasty.[4] These findings indicated that even with maximal correction of the subclavian lesion, there was a substantial delay (20 sec to more

TABLE I. Primary Patency for Stent Deployment in 16 Patients with Subclavian Occlusions

Interval (months)	No. of Stents at Risk	No. of Failed Stents	No. Withdrawn Patent Due to			Interval Patency Rate	Cumulative Patency (%)	Standard Error (%)
			Duration	Loss to Follow-up	Death			
0-1	21	0	0	4	0	1.00	100	0
1-3	17	0	0	0	0	1.00	100	0
3-6	17	3	2	0	0	0.81	100	0
6-9	12	0	1	0	0	1.00	81	10.1
9-12	11	0	2	0	1	1.00	81	10.6
12-15	8	0	3	0	0	1.00	81	12.4

than 30 min) in the re-establishment of antegrade flow in the vertebral artery. This delay protects the vertebral territory from thromboembolic complications by deflecting any emboli into the upper extremity rather than the cerebral circulation. It is important to note that the protective effect is present only in patients with a preoperative retrograde flow in the vertebral artery. In our study, all patients presented with either persistent retrograde vertebral flow or vertebral occlusion, and none developed thromboembolic complications.

Although our series comprised a small number of patients, stenting of subclavian occlusions in this population resulted in remarkable procedural success that yielded satisfactory intermediate-term improvement in patency and symptoms compared with published results of angioplasty.[3] There were no significant complications associated with treatment. Restenosis during follow-up can be managed by an intraluminal approach with the same low rates of morbidity and mortality. If repeat endovascular treatment fails, surgical intervention can always be undertaken.

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