Percutaneous Revascularization of Atherosclerotic Obstruction of Aortic Arch Vessels

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OBJECTIVES
To compare stenting of aortic arch vessel obstruction with surgical therapy and to establish recommendations for treatment.

BACKGROUND
Though surgery has been considered to be the procedure of choice for subclavian and brachiocephalic obstruction, little work has been done to compare it with stenting.

METHODS
Eighteen patients with symptomatic aortic arch vessel stenosis or occlusion were treated with stenting, followed by periodic clinical follow-up and noninvasive arterial Doppler studies. Data were compared with the results as shown in a systematic review of a published series of surgery and stenting procedures which included comparison of technical success, complications, mortality and patency.

RESULTS
Primary success in our series was 100% with improvement in mean stenosis from $84 \pm 11\%$ to $1 \pm 5\%$ and mean arm systolic blood pressure difference from $44 \pm 16$ mm Hg to $3 \pm 3$ mm Hg. There were no major complications (death, stroke, TIA, stent thrombosis or myocardial infarction). At follow-up (mean 17 months), all patients were asymptomatic with 100% primary patency. Literature review demonstrates equivalent patency and complications in the other published series of stenting. In contrast, there was a similar patency but overall incidence of stroke of $3 \pm 4\%$ and death of $2 \pm 2\%$ in the published surgical series.

CONCLUSIONS
Subclavian or brachiocephalic artery obstruction can be effectively treated by primary stenting or surgery. Comparison of stenting and the surgical experience demonstrates equal effectiveness but fewer complications and suggests that stenting should be considered as first line therapy for subclavian or brachiocephalic obstruction. (J Am Coll Cardiol 1999;33:1238–45) © 1999 by the American College of Cardiology

Brachiocephalic or subclavian artery obstructions account for approximately 17% of symptomatic extracranial cerebrovascular disease (1,2) and are an important cause of morbidity associated with a variety of symptoms. Subclavian steal syndrome arises when flow reversal occurs in the vertebral artery thereby shunting blood away from the brain and into the brachial circulation (1,3,4) resulting in the symptoms of vertebrobasilar insufficiency (2,5). Upper extremity ischemic symptoms may occur as a result of ipsilateral claudication related to arm exercise or from embolization of the digits (6). In coronary-subclavian steal there is a proximal subclavian stenosis causing reversal of flow in an internal mammary artery graft and ischemia of the myocardium it supplies (7–10). The prevalence of subclavian artery stenosis in patients undergoing myocardial revascularization is approximately 0.5% to 1.1% (10–12). Similarly, patients who undergo axillofemoral bypass surgery may have unrelied claudication or graft compromise due to an unrecognized proximal subclavian stenosis.

Although some patients may become asymptomatic (13,14) with conservative therapy, the majority require relief of the obstruction to alleviate symptoms. A variety of surgical techniques have been developed including trans-thoracic procedures, carotid-subclavian bypass and axilloaxillary bypass (2,21–71). Over the years these surgical approaches have been considered “standard” therapy. However, even with less invasive extraanatomic extrathoracic reconstructions, the morbidity and mortality is significant (2,21–71).

Balloon angioplasty for subclavian artery stenosis was first described in 1980 (15). Comparatively favorable initial success and patency were achieved with rare complications and mortality (15–20). The potential for distal embolization and stroke, uncertain long-term patency and difficulty in treating total occlusions remained a concern. Recognizing improvements in anesthetic and operative technique, short

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hospital stays and early discharge, many practitioners continued to regard surgery as the standard therapy against which endovascular methods must be compared.

Vascular stenting has reduced acute closure, diminished distal embolization, improved medium term patency and provided the ability to recanalize chronic total occlusions. As a result, enthusiasm has developed for the use of vascular stents as primary treatment for atherosclerotic obstructive disease of branches of the aorta. Unfortunately, there have been no randomized trials comparing percutaneous interventions with surgery for treatment of aortic arch vessel disease. This report describes what is known about surgical treatment outcomes and compares these results with our experience in using of the Palmaz stent for the primary treatment of patients with symptomatic subclavian or brachiocephalic artery obstruction.

METHODS

Patients. All patients referred to the Interventional Cardiovascular Medicine Service between November 1994 and March 1998 were screened for the presence of symptomatic brachiocephalic or subclavian artery obstruction. Eighteen persistently symptomatic patients who required revascularization were identified. A percutaneous treatment approach was chosen in all 18, including 4 with total occlusions. Table 1 summarizes the baseline clinical characteristics of these patients.

Symptoms were classified according to the following scheme: neurological manifestations of subclavian steal comprised the syndrome of vertebrobasilar ischemia with ipsilateral retrograde vertebral artery blood flow in the presence of subclavian or brachiocephalic occlusive disease proximal to the origin of the vertebral artery. In patients in whom the internal mammary artery had been used for coronary bypass, myocardial ischemia was attributed to subclavian-coronary steal if the origin of the artery was distal to the subclavian obstruction and there were no other angiographic coronary obstructive lesions that might account for the symptoms; in addition, coronary angiography revealed retrograde filling of the internal mammary artery. Upper extremity ischemia, occurring in seven patients, was manifest by severe exertional arm claudication (n = 5) or clinical evidence of digit emboli (n = 2). There was one patient who underwent axillofemoral bypass surgery for critical lower limb ischemia but had persisting graft inflow obstruction because of a severe proximal right subclavian artery stenosis.

All patients underwent clinical evaluation and noninvasive vascular assessment with a Doppler ultrasound study of the brachiocephalic vessels including measurement of the brachiobrachial index (the ratio of the systolic pressure of the affected arm over that of the opposite arm). The index can only be calculated if the contralateral “normal” arm shows no Doppler evidence of obstruction. Carotid duplex scanning was performed to detect other extracranial vessel involvement and to determine the direction of flow in the vertebral arteries at rest.

Before revascularization nine patients were pretreated with 325 mg of aspirin daily in combination with 250 mg of Ticlopidine twice daily; five patients received aspirin alone. Four patients were receiving long-term warfarin (for indications unrelated to stenting) and this was reinstituted (in combination with aspirin) following the procedure.

Revascularization procedures. Using standard catheterization techniques, arterial access was obtained (femoral 12, brachial 2, radial 1 and femoral-brachial 3). Aortic arch and selective angiography were performed in at least two views that displayed the lesion. Intravenous heparin was administered during the procedure to maintain the activated clotting time in the range of 200 to 300 s. An appropriate guiding catheter was chosen and the stenosis crossed with an 0.018” guidewire. Predilatation was accomplished using a balloon undersized by 1–2 mm.

In the case of total occlusions, the obstructions were
traversed using 0.035 to 0.037 Glidewires (Meditech, Boston Scientific Inc., Natick, Massachusetts) over which were passed a 4 or 5 Fr Glidewatch (Meditech, Boston Scientific Inc., Natick, Massachusetts). The intravascular position of the catheter was confirmed by contrast injection and a 0.018” guidewire was then placed through the catheter. Initial dilatations were carried out progressively beginning with 4 mm balloons. All patients then received Palmaz stents (P104, P154, P204, Johnson & Johnson Interventional Systems) which were hand-crimped on balloons estimated to be sized 1:1 to the reference segment. When necessary, multiple stents were placed to cover the entire stenosis. Following initial stent deployment, high-pressure inflations (10–16 atm.) were performed. Final angiograms were obtained in projections identical to those used initially. All vascular sheaths were removed the same day as the procedure.

Quantitative angiographic measurements were made in the view showing the most severe disease. Digital calipers were used to measure the reference diameter (RD) of the nearest uninvolved segment and minimal luminal diameter (MLD) of the diseased segment. The contrast-filled guiding catheter was used for calibration. Percent stenosis is expressed as: \( \left[ \frac{RD - MLD}{RD} \right] \times 100 \).

Follow-up with clinical evaluation and repeat noninvasive arterial studies were planned within 1 to 6 weeks, at 6 months, at 12 months and subsequently at yearly intervals after the procedure. The stented segment was judged to be patent if there was no recurrence of symptoms, mean systolic BP difference between the arms was <10 mm Hg and the stent velocity by Doppler increased by no more than 20% with an absolute measurement of <200 cm/s.

**Literature review and analysis.** A Medline search was performed to identify all papers and abstracts discussing surgery for subclavian, brachiocephalic, cervical or aortic arch vessels. The period searched encompassed 1966 through 1998. Over 300 citations were screened to identify papers where the surgical treatment of obstructive atherosclerotic vascular disease was the primary focus. Each paper was reviewed, and the references were screened for other papers not previously identified in the Medline search. Where multiple similarly authored papers included the same series, the most recent or the one containing the largest series was chosen. Single case reports were reviewed as sources of other papers contained within their references but were not included in the analysis.

Qualitative comparisons of the published surgical outcomes and stent outcomes were made. Both the diagnostic criteria in these collected series and the definitions of “complications,” “minor complications” and “major complications” varied from series to series. Follow-up protocols, criteria for symptom recurrence and the determination of patency were often not stated. Therefore it was decided that we would evaluate simpler but more uniformly reported endpoints including technical success (the ability to perform the planned procedure yielding target lesion revascularization and survival to discharge), patient death, stroke and patency of the treated segment.

**RESULTS**

**Current series.** There were 18 treated segments (4 occlusions, 14 high-grade stenoses) in 18 patients with a mean residual stenosis after stenting of 1 ± 5% and appearance of normal antegrade flow in the treated vessels. The procedural minimal luminal diameter was 1.2 ± 0.8 mm increasing to 7.4 ± 1.2 mm after stenting, for an acute gain of 6.2 mm. Mean stent length was 27 ± 14 mm (range 15 to 60 mm). The mean poststent balloon diameter was 8 ± 1 mm (range 5 to 10 mm) with a mean inflation pressure of 16 atmospheres. A typical angiographic result illustrating recanalization and stenting of a chronic total subclavian occlusion is shown in Figure 1A and B. The systolic blood pressure difference between the arms decreased from 44 ± 16 mm Hg to 3 ± 3 mm Hg (Fig. 2) and the brachiocephalic index increased from 0.70 ± 0.11 to 0.98 ± 0.02. All 18 patients reported complete relief of their presenting symptoms.

There were no major complications (death, stroke, transient ischemic attacks, myocardial infarction, stent thrombosis or occlusion). An access site pseudoaneurysm developed in one patient; this was successfully compressed using ultrasound guidance. Stent embolization occurred in one patient; the stent was withdrawn to the femoral artery and then surgically retrieved.

During the 1 to 48 month follow-up (mean 17 months), symptomatic restenoses did not occur and the brachiocephalic gradient did not change (Fig. 2). All Doppler studies were consistent with widely patent vessels. One patient died 12 months after intervention from causes unrelated to her procedure. There were no repeat interventions at the treated segment, but two additional patients later underwent successful stent placement to the iliac artery for symptomatic lower limb ischemia.

**Surgical review.** Table 2 summarizes the 52 papers that describe a total of 2,496 patients treated surgically. In these reports, preprocedure symptoms, diagnostic evaluation and concomitant medical illnesses were not consistently described. The methods by which one procedure was chosen over another were variable and the rationale for performing (or not performing) associated carotid endarterectomy in patients with combined carotid disease were not uniformly stated. There were no prospective randomized trials comparing surgery with any other form of therapy or comparing different surgical procedures.

The combined initial technical success rate is high (mean 96 ± 5%, range 75% to 100%). Stroke occurred in 3 ± 4% (range 0% to 14%) and death in 2 ± 2% (range 0% to 11%). Adverse events of any kind were reported in 331 patients for an overall complication rate of 16 ± 11% (range 0% to 43%) (2,21–71). When the review is limited to surgical series
from the last ten years, complications occur in 13%, stroke in 3% and death in 2% (57–71).

Reported surgical complications included stroke or transient ischemic attack, myocardial infarction, hemorrhage, phrenic nerve palsy, Horner’s syndrome, delayed wound healing, infection, graft thrombosis, lung atelectasis with pneumonia, pleural effusions, chylothorax and others pertaining to general anesthesia. Risk factors associated with complications suggest that open-chest procedures are associated with a higher mortality and morbidity than that of extrathoracic bypass (2,23,27,71) and that current surgical practice favors local bypass with synthetic conduit.

Follow-up was largely clinical in the surgical series and while this may have been adequate to identify symptom recurrence, it does not confirm patency of the treated segments; the development of collaterals may mask the brachiocephalic pressure differential of a stenosed or occluded bypass. Overall recurrence was reported in 268 patients (16 ± 14%) at a mean follow-up of 51 ± 25 months. Recurrence in surgical series reported in the last ten years is 12%. Because Doppler evaluation is required to confirm triphasic subclavian flow or graft patency in these situations, these are largely clinical threshold recurrence rates, and the true rates of restenosis or occlusion may be higher.

Stent review. Table 3 summarizes the published series of patients treated with stents. Of the 108 patients represented in the reports (72–77), technical success was achieved in 105 (97 ± 4%). Adverse events were reported in 7 patients (6 ± 5%). In contrast to surgery, reported complications with stenting were minor and limited to vascular access difficulty and stent dislodgment, which was managed by deployment at the iliac artery or by surgical retrieval of the stent via the catheter entry site. No strokes or deaths were reported. Follow-up data were available in 81 of 108 procedures at a mean duration of 20 ± 9 months. Recurrence (documented reocclusion or restenosis) was reported in 3 ± 5%.

DISCUSSION

Surgery as standard therapy. Before the advent of percutaneous techniques, surgical treatment for aortic arch vessel obstruction was advocated with axilloaxillary and carotid-subclavian bypass as the favored procedures due to relatively low morbidity and mortality. Despite this, surgical proce-
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<td>2</td>
<td>2</td>
<td>16</td>
<td>15</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Berguer</td>
<td>71 1998</td>
<td>96</td>
<td>10</td>
<td>10</td>
<td>41</td>
<td>41</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2496</td>
<td>2184</td>
<td>70</td>
<td>331</td>
<td>53</td>
<td>268</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MEAN: 48% 96% 3% 16% 2% 16% 51%**

**RANGE: 6–221 75–100% 0–14% 0–43% 0–11% 0–50% 3–120**

**S.D: 42 5 4 11 2 14 25**

AAB = Axillo-axillary bypass; CSB = Carotid-subclavian bypass; TRP = Carotid-subclavian transposition; BYP = Other bypass procedure; VL = Vertebral ligation; EAC = Endarterectomy; TT = Transthoracic approach; Ref. = Reference number; F/U(mo.) = mean follow-up (months).
dures are still associated with significant risks including a rate of stroke of approximately 3% and mortality of 2%.

**Benefits of percutaneous treatment.** Percutaneous catheter-based treatment has become an alternative to surgery because it is less invasive, has a lower complication rate and may result in a shorter hospitalization. Several earlier studies have reported initial success and patency rates with balloon angioplasty similar to surgery (15–20). Stenting, when used in addition to balloon dilatation, may reduce the risk of embolization and achieve anatomically and physiologically superior results. Indeed, analysis of the literature (72–77) suggests that complications are fewer and the success of revascularization similar, if not better. The treatment of total occlusions, thought to be a limitation of percutaneous treatment, is now possible (72). Good results are also being reported with stent-based treatment of carotid stenoses (78).

Our series consists of all patients with subclavian and brachiocephalic obstruction identified by or referred to our unit over the course of 48 months; all were treated using percutaneous techniques employing stents to revascularize patients with symptomatic stenoses and occlusions. There was uniform success and few complications—notably no transient or permanent neurological deficits and no deaths. Follow-up evaluation was standardized and objective—100% patency of the treated segments was confirmed by noninvasive testing. This format ensured that occlusions or restenoses were not masked by the development of collateral circulation. The results of percutaneous stenting compare favorably with the surgical experience. Specifically, technical success (97% vs. 96%) and patency (97% at 20 months vs. 84% at 51 months) are similar while the incidence of the major complications of stroke and procedure–related death are lower in the stent group.

**Limitations of this study.** Care must be taken in drawing conclusions from the published experience of any procedure for brachiocephalic and subclavian revascularization. There are no prospective randomized clinical trials comparing the two forms of therapy; all published series are descriptions of experience. Since the reported series are not themselves controlled trials, a combined metaanalysis is not appropriate. Comparison is also confounded by the lack of similar patient selection criteria, inclusion bias or recorded endpoints. It is also inappropriate to combine the surgical series into one group as “historical controls” and the stented patients into a second “treatment group” and to compare statistically their mean characteristics.

The length of time over which the surgical literature has been developed gives rise to questions of whether it is appropriate to compare the surgical techniques of the past few decades with the percutaneous treatment of the past few years. Though surgical techniques have improved, operations still often involve general anesthesia, direct manipulation or clamping of the carotid (in the case of carotid-subclavian bypass) or open-chest procedures—perhaps accounting for the potentially higher rates of overall complication and stroke with surgical treatment. When only the surgical series from the last ten years are considered, the rates of overall complications, stroke and death still appear to be greater than those of stenting.

**Conclusions.** Considering our clinical results and the available published data, surgical therapy does not appear to provide outcomes superior to those of percutaneous stenting. The absence of stroke or death in the stent series strongly suggests that, in experienced hands, stenting may achieve its outcomes at a lower procedural risk than surgical therapy. Until a large-scale prospective randomized trial can be performed, we believe percutaneous stenting should be considered the preferred therapy for the treatment of aortic arch vessel obstructive lesions.

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