Long-term treatment outcomes after intravascular ultrasound (IVUS) evaluation and stent placement for atherosclerotic subclavian artery obstructive lesions

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Abstract

[BACKGROUND AND PURPOSE] The objective of this study was to determine long-term outcomes after stent placement for subclavian artery (SA) obstructive lesions assisted by intraoperative intravascular ultrasound (IVUS).

[METHODS] This study included 25 lesions of 24 patients -who underwent stent placement assisted by intraoperative IVUS for subclavian artery stenosis or obstruction at our hospital between January 2003 and and August 2010. Outcome was evaluated based on the results within 30 postoperative days (technical success rate, improvement in upper extremity ischemia, steal syndrome, and left-right blood pressure difference; and perioperative complications) and the results after 30 postoperative days (incidence of vertebrobasilar artery territory infarction and restenosis).

[RESULTS] Stent placement and vessel dilatation were successful in all patients, without perioperative complications. Upper extremity ischemia, steal syndrome, and left-right blood pressure difference were disappeared in all cases. During follow-up observation (6-96 months; median 51 months), no restenosis occured at the stent placement site in any patient. In one case, 4 years after initial treatment, stenosis was noted proximal to the stent placement site.

[CONCLUSION] Satisfactory long-term as well as short-term outcomes were achieved after stent placement for SA obstructive lesions assisted by intraoperative IVUS evaluation.

ABBREVIATIONS:

SA = subclavian artery; IVUS = intravascular ultrasound

Introduction

Percutaneous revascularization for SA stenosis and obstruction can be performed under local anesthesia and has fewer complications than more highly invasive open surgery[1, 2]. Therefore, percutaneous revascularization has assumed a role in the early treatment of SA lesions. Since the 1990s, with advances in devices and techniques, recanalization by stent placement can be performed not only for stenosis, but also for complete obstruction, of the SA[2]. IVUS provides greater understanding of blood flow, vessel lumen and media size, and the interface between the vessel wall and the blood stream. Using IVUS have improved to understand the arterial disease they are treating and to assess the completion of treatment. Although feasible early outcomes have already been reported for percutaneous revascularization in SA, there are few reports of long-term outcomes, and in our literature search, no reports of evaluation and revascularization of SA lesions using intraoperative IVUS assistance were found. The purpose of the current study is to investigate the short term and long term treatment outcomes of the cases in which stent placement for SA stenosis were made with assistance by intraoperative IVUS evaluation.

Methods

This study included 24 patients (25 lesions) who underwent stent placement for SA stenosis or obstruction by using intraoperative IVUS evaluation at our hospital between January 2003 and August 2010. The indications for treatment were symptomatic lesions or ≥70% stenosis. There were 20 men and 4 women, ranging in age from 56 to 80 years (median, 69 years). Twenty-one lesions were stenotic (stenosis 70-99%; mean, 82%),

and 4 lesions were completely obstructed. Eleven lesions were symptomatic (upper extremity ischemia 7, subclavian steal syndrome 2, stroke 1, transient ischemic attack (TIA) 1), and 14 lesions caused only mild arm claudication. The preoperative blood pressure difference was 15-30 mmHg (mean, 21 mmHg).

Patients received two oral antiplatelet drugs (aspirin 100 mg/day; and clopidogrel 75 mg/day or cilostazol 200 mg/day or ticlopidine 200 mg/day) from at least 3 days before treatment. The endovascular procedure was performed under local anesthesia in all patients, with systemic heparinization to keep the activated coagulation time (ACT) at 2 to 3 times normal. A femoral artery approach and/or brachial artery approach was used (femoral artery approach alone in 18 lesions and combined with the brachial artery approach in 6 lesions). The procedure was performed with the brachial artery approach alone in 1 case due to severe aortic tortuosity and bending. In the femoral artery approach, a pull-through technique[3] was used in 2 cases. In the femoral artery approach, a standard 9-Fr guiding catheter was used, and in the brachial artery approach, a 6-Fr guiding sheath was used. Distal protection of vertebral artery (VA) was used in 5 cases, due to the ipsilateral VA dominant, since the protection devices were available. The VA was protected with a balloon catheter ; using Hypergride (ev3 Neurovascular, Irvine, CA, USA) in 4 cases and Equinox (MTI, Irvine, CA, USA) in 1case. Post-dilation was performed using a PTA balloon with a diameter not exceeding the normal luminal diameter just distal to the stenosis, as measured by IVUS.

After placement of the guiding catheter at the origin of the SA, IVUS was performed to assess lesion extent, configuration, degree of calcification (defined as none, no calcification; little, <1/3 circumference; moderate, 1/3 to 2/3 circumference; and severe, >2/3 circumference), site of stenosis, and preoperative vessel diameter correctly.

Subsequently, predilation with a 3.0-mm-diameter balloon was performed, followed by stent placement. We used the information from IVUS for stent selection as follows. When stenosis involved the SA origin, we used balloon-expandable stent Palmaz stent (Cordis Endovascular, Miami Lakes, FL, USA) in 17 lesions and an Express stent (Boston Scientific, Natick, MA, USA) in 2 lesions. When the stenosis was ≥1 cm from the SA origin, a self-expandable stent (Smart Control (Cordis Endovascular) (4 lesions); Luminex stent (Bard, Murray Hill, NJ) (1 lesion); or Easy Wallstent (Boston Scientific) (1 lesion) was used. Regarding selection of stent diameter and length for placement, the stent diameter (fully open) was ≥1 mm larger than the internal diameter of the normal proximal SA, and the stent length was sufficient for the stenosis to be covered by the stent.

We evaluated incidence of perioperative complications (symptomatic/asymptomatic infarction). Short term outcome were evaluated on the results within 30 postoperative days, including the technical success rate (defined as ≤30% residual stenosis), degree of calcification on IVUS (defined as none, no calcification; little, <1/3 circumference; moderate, 1/3 to 2/3 circumference; and severe, >2/3 circumference). Rate of improvement in upper extremity ischemia (diagnosed when the patients complain with disabling exertional arm discomfort), steal syndrome (diagnosed by retrograde vertebral artery blood flow on digital subtraction angiography), and left-right BP difference (defined as BP difference of >20 mmHg between the two arms and improvement defined as BP difference of ≤10 mmHg) were also evaluated. Long term outcome were evaluated on the results after 30 postoperative days, including recurrence of symptoms during clinical follow-up, incidence of infarction on imaging follow-up, and incidence of restenosis (defined as stenosis ≥70%).

Two antiplatelet drugs were continued for at least 1 month after treatment. Within 12 months of treatment, imaging by computed tomography angiography (CTA) or digital subtraction angiography (DSA) was performed. Thereafter, patients were followed with periodic imaging.

Results

Short term outcome (within 30 postoperative days)

There were no perioperative complications. Stent placement and vessel dilatation were successful in all patients. Residual stenosis was 0-10% (mean, 2.6%) on DSA and 5-19% (mean, 8.6%) on IVUS (Table 1). The degree of calcification on IVUS was: none, 1 (4%); little, 23 (92%); moderate, 1(4%); and severe, 0 (0%) (Table 2). In all 24 patients who had been symptomatic, upper extremity symptoms and the steal syndrome, which had been present preoperatively, disappeared. In all patients, the left-right (arm) BP difference also improved (≤10 mmHg).

Long term outcome (after 30 postoperative days)

During follow-up observation (6-96 months; median, 51 months), no recurrence of symptoms or no symptomatic/asymptomatic infarctions occurred. During imaging follow-up (CTA 17, DSA 8; 12-80 months; median, 24 months), no restenosis at the stent placement site was observed in any patient (Fig. 1, 2). In one case (5%), 4 years after initial treatment, stenosis was noted proximal to the stent placement site. Retreatment (PTA and stent placement) was performed, and the stenosis disappeared (Fig. 3).

Discussion

About surgical treatment and outcomes in subclavian artery stenosis, in some studies were reported perioperative mortality rate of 0 - 1.8%, ischemic complication rate of 0 - 8%, and a 5-year primary patency rate of 83- 95%[4, 5, 6, 7, 8]. With surgical treatment, although the incidence is low, perioperative complications and mortality, as well as symptom recurrence, have been reported.

Although PTA for SA is treatment of the choice in the case with SA stenosis or occlusion in these days, there is still some instance with complication related to the procedure. Of 107 cases (108 lesions) reported by Sixt et al.[9], the technical success rate was 96% (100% for stenosis (78/78) and 87% for total occlusions (26/30)), treatment modalities included PTA alone (13%) or stenting (87%), and the mortality rate and morbidity rate were both 0%. Patel et al.[10], in a study of 170 cases (177 lesions) reported a technical success rate of 98.3% (99.4% for stenosis (155/156) and 90.5% for occlusions (26/30)), all underwent primary stent placement, and stroke in 1 patient (0.6%, not described about distal protection of vertebral artery). Thus, technical rates were high, and perioperative complication rates were low. In the 25 lesions, the technical success rate was 100%, morbidity was 0%, with no ischemic complications in the current study, and mortality was 0%. Therefore, regarding early outcomes, the present results are similar or better than those reported to date.

About endovascular treatment and mid- and long-term outcomes, Brountzos et al.[2], of 39 cases followed up, reported that 10.2% required retreatment for restenosis during

the follow-up period. Patel et al.[10], of 151 cases followed up, reported that, during a mean observation period of 35.2 months, 14.6% required retreatment. Sixt et al., of 97 cases followed up, reported that, during a mean observation period of 29 months, 12% required retreatment. The primary patency rate was 88% after 12 months. Thus, restenosis and retreatment rates were about 10%. Of the present cases, in which IVUS assistance have applied, none had restenosis. In one case (4%), 4 years after initial treatment, 85% stenosis proximal to the stent placement site was noted. For this stenosis, PTA and stent placement were performed, and the stenosis disappeared. During subsequent follow-up (20 months), restenosis had not occurred. Therefore, after treatment, follow-up observation is necessary for not only at the stent placement site, but also at the vessel proximally and distally.

Amor et al.[11] compared direct stenting (22 cases) of lesions with little calcification and a relatively preserved lumen and stent placement after predilation (54 cases) for obstruction or stenosis associated with severe calcification and tortuosity. Restenosis with direct stenting occurred in one case (4.76%), whereas with stent placement after predilation, restenosis occurred in 14 cases (28.5%). They assumed that the lesions with severe calcification were difficult to get sufficient dilatation, thus the restenosis occurred more likely in such lesions. Motarjeme et al.[12], in a study of 13 cases of complete obstruction, reported a technical success rate of 46% and a very high restenosis rate of 50% after 1 year; whereas among cases where good dilation was achieved immediately after dilation, there was no restenosis. On the other hand, de Vries et al.[4], of 102 cases that included 20 complete obstructions, reported that, during a mean follow-up period of 34 months, there was significant restenosis (≥70%) in 8 cases (7.8%). However, for obstructed lesions, no significant restenosis was observed, so they

stated that the factors causing restenosis were unknown. And in our literature search, no reports of evaluation and revascularization of SA lesions using intraoperative IVUS assistance were found.

In the cases of the current study, including 21 stenotic lesions and 4 obstructed lesions, stent placement was performed after predilation, and restenosis at the stent placement site did not occur in any case during follow-up observation. Among all stenotic lesions and obstructed lesions, severe calcific stenosis, which would make stent placement difficult, was not observed by IVUS in our cases. In all cases, the site of stenosis and areas proximal and distal to the lesion were assessed by IVUS, and a stent was placed to sufficiently cover the plaque at the stenotic site. The degree of dilation after stent placement was assessed not only by DSA, but also by IVUS. Residual stenosis was 0-10% (mean, 2.6%) on DSA and 5-19% (mean, 8.6%) on IVUS. Good dilation was confirmed in all cases.

We believe that one reason for the absence of restenosis in any of the present cases was that the entire stenotic site could be sufficiently covered by stent placement, and good dilation could be confirmed using intraoperative IVUS. The absence of lesions with severe calcification, which make stent placement difficult, may be one of the reasons for low restenosis rate in our population. If more patients who had obstructive lesion with moderate or severe calcification were enrolled, the outcomes might be different from the present results.

Guidelines published by the American Heart Association (AHA) in 2011[13] generally recommend conservative treatment for SA obstructive lesions and state that the indications for a revascularization procedure should be carefully considered. However, in patients with severe upper extremity ischemia, subclavian steal syndrome, or

vertebrobasilar artery ischemia, and when blood supply from collateral circulation cannot be expected, revascularization should be considered to improve ischemic symptoms and prevent stroke. This study includes asymptomatic cases treated before AHA guidelines were published. Although this study showed no perioperative complications and good long-term outcome, indication to stent placement for asymptomatic SA stenosis should be considered carefully.

There are a number of limitations in this study. Limitations were following: 1) This study was retrospective and the non-randomized design with a rather small sample size 2) This study was no comparative study between using IVUS technique and not using IVUS technique. 3) This study was performed in a single center and all procedures were performed by the same experienced interventional team. Although this study had a number of limitations, the effectiveness of stent placement assisted by IVUS evaluation for SA obstructive lesions was suggested for good long-term result. A prospective comparative study involving a greater number of patients may be needed in the future to properly assess these results.

Conclusion

With IVUS evaluation and stent placement for SA obstructive lesions, our long-term treatment outcomes were very good. Assessment of lesion extent and lesion characteristics using intraoperative IVUS may be useful in reducing the incidence of restenosis.

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Table 1. Lesion characteristics on IVUS and stent device

Case	Lesion characteristics	Pre-MLD (short axis) (mm)	Stent	Post-MLD (short axis) (mm)	Residual stenosis (%)
1	Obstructive	0	Palmaz	5.5	10
2	Regular	2	Palmaz	7	5
3	Regular	2.8	Palmaz	6.1	5
4	Irregular	2.6	EasyWall	5.9	10
5	Irregular	3.1	Palmaz	5.8	15
6	Irregular	3.3	Palmaz	6.6	14
7	Irregular	3.4	Luminex	4.6	5
8	Regular	3.2	Palmaz	7.4	7
9	Irregular	1.8	Palmaz	7.7	5
10	Irregular	1.6	Palmaz	5.7	5
11	Irregular	3.7	Palmaz	7.8	10
12	Regular	2.3	Palmaz	7.1	10
13	Irregular	2.2	SmartControl	6.7	3
14	Regular	3.4	Palmaz	6.8	5
15	Obstructive	0	SmartControl	5.4	10
16	Irregular	0.8	SmartControl	7.8	7
17	Irregular	1.8	Express	5.2	17
18	Irregular	2	Palmaz	8.4	0
19	Regular	1.6	Palmaz	5.6	19
20	Irregular	1.8	Palmaz	3.5	14
21	Regular	5.4	Palmaz	7.7	7
22	Regular	2	Palmaz	7.7	5
23	Regular	0.7	Express	6.7	10
24	Obstructive	0	Palmaz	7	0
25	Obstructive	0	SmartControl	4.7	7

MLD: minimum lumen diameter

Table 2. Distribution of target lesion calcification on IVUS

None (n, %)	1 (4)
Little (n, %)	23 (92)
Moderate (n, %)	1 (4)
Severe (n, %)	0 (0)

None, no calcification; little, <1/3 circumference; moderate, 1/3-2/3 circumference; severe, >2/3 circumference

Fig. 1. A 56-year-old man suffering from arm ischemia.

(A) Digital subtraction angiography (DSA) depicts a high grade stenosis at the orifice of left subclavian artery (*arrow*). (B) DSA after placement of Palmaz stent depicts elimination of the stenosis (*arrow*). (C) The luminal diameter of the site of stenosis and areas proximal and distal to the lesion measured by IVUS. (D) After stent placement, IVUS shows the stent to be placed to sufficiently cover the plaque at the lesion. (E) On CTA after 1 year shows good patency (*arrow*).

Fig. 2. A 67-year-old woman with developing arm ischemia.
(A, B) DSA and depicts total occlusion at the orifice of left subclavian artery (*arrow*). (C) Post DSA reveals adequate result after balloon angioplasty and deployment of Palmaz stent (*arrow*). (D, E) On CTA after 3 months shows good patency (*arrow*).

Fig. 3. A 80-years-old man performed stent placement for left subclavian artery stenosis. 4 years after the first procedure, the stenosis progressed at the ipsilateral subclavian artery orifice. (A) CTA shows high grade stenosis proximal to the 1st stent (*arrow*). (B) Aortic arch DSA after placement of Express stent depicts elimination of the stenosis (*arrow*).