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CLINICAL INVESTIGATION

Initial and Long-Term Results of Endovascular Therapy for Chronic Total Occlusion of the Subclavian Artery

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Abstract
Purpose To study the initial and long-term results of angioplasty and primary stenting for the treatment of chronic total occlusion (CTO) of the subclavian artery (SA).
Materials and Methods From January 1999 to February 2010, 56 patients (25 men with a mean age of 58 ± 8 years) underwent endovascular treatment for CTO of the SA. Duplex scans and arteriograms confirmed occlusion in all cases. Indications for recanalization were subclavian steal syndrome in 33 patients (58.1%), arm claudication in 13 patients (23.2%), and coronary ischemia in 7 patients (12.5%) who had a history of previous coronary artery bypass grafting that included left internal thoracic artery graft. Three patients (5.4%) were treated before the scheduled coronary artery bypass surgery, which included left internal thoracic artery graft. After successful recanalization, all arteries were stented, and all of the patients were followed-up at 1, 3, 6, and 12 months after surgery and annually thereafter.
Results Successful recanalization of the SA was achieved in 46 patients (82.1%), and the complication rate was 7.1%. During follow-up (mean 40 ± 26 months; range 2 to 125), the primary patency rates after 1 and 3 years were 97.9% and 82.7%, respectively. At the end of follow-up, 76% of the arteries showed no evidence of restenosis. Univariate analysis failed to identify any variable predictive of long-term patency of successfully recanalized SA.
Conclusion Percutaneous transluminal angioplasty with stenting of the complete total occlusion of the SA is a safe and effective procedure associated with low risks and good long-term results.

Keywords Clinical practice · Angioplasty/angiogram · Subclavian artery · Chronic total occlusion · Recanalization · Peripheral vascular · Arteriosclerosis · Occlusion

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Introduction

Obstruction of the subclavian artery (SA) is an important cause of symptomatic extracranial cerebrovascular disease [1]. Symptoms that may arise from the obstruction of the SA include vertebrobasilar ischemia, upper limb ischemia, hand claudication, digital embolization, and angina in patients with a left internal thoracic artery (LITA) graft [2–8]. Additional indications include increased inflow for scheduled coronary artery bypass surgery (LITA graft) [9]. These symptoms also are generally considered as indications for either surgical or endovascular treatment. During the last 40 years, a number of surgical techniques have been developed for SA reconstruction. However, even with less invasive extrathoracic procedures, the reported mortality rate is 2% to 5%, and the total complication rate is ≤15% [10–13]. Percutaneous transluminal angioplasty (PTA) has evolved as an effective and safe treatment

modality for occlusive lesions of the SA since the 1980s [14–17].

Most of the published articles report on PTA and stenting for SA stenosis; however, chronic total occlusion (CTO) of the SA intervention has been confined to a few small case series [5, 18, 19]. The current study was undertaken to review our 11-year experience of SA recanalization with stenting and to evaluate the safety, short- and long-term patency, clinical success rates, and predictive risk factors in patients with CTO of the SA.

Patients and Methods

From January 1999 to February 2010, 56 consecutive patients underwent endovascular treatment for CTO of the SA at the University Cardiovascular Clinic. All of the patients except 3 (who were prepped for coronary artery bypass graft (CABG)–LITA graft) were symptomatic. Patients with arteritis, aneurysm, and pseudoaneurysm were excluded from the analysis. In patients with long occlusions (>5 cm) combined with severe calcification, and in patients with occlusions close to the vertebral artery ostium, surgical revascularization was considered the optimal primary treatment.

Preoperative evaluation included extracranial carotid arteries duplex ultrasound scanning as well as subclavian and vertebral arteries and segmental pressure measurement of both upper limb arteries. From 1999 to 2005, digital subtraction angiography (Siemens, Erlangen, Germany) (15 patients) was used, and multislice computed tomography (MSCT) angiography (Lightspeed VCT; GE Healthcare, Milwaukee, WI, USA) has been used since 2005 (41 patients). It is a general policy at our institution that on admission, patients must sign an informed consent that allows the use of their data for retrospective analysis. Also, approval from the local Ethical Committee for the particular study was obtained.

Interventional Procedure

The interventional procedures were performed in the angiography suite by interventional radiologists after consultation with the attending vascular surgeon. All procedures were performed with the patient under local anesthesia. The subjects received a bolus of 100 IU/kg heparin before treatment. An 8F or 9F sheath or guiding catheter was used for femoral approach, whereas a 5F or 6F introducer was used for arm (radial/brachial) approach. In a case of an nonostial occlusion of the SA, the transfemoral approach was attempted initially. Retrograde approach was used in patients with extensive aortoiliac disease or in patients with ostial occlusion. In this series, combined approach was most frequently used, i.e., the occlusion lesion was crossed from the radial or brachial approach. We used guidewires and guiding catheters used for coronary intervention: 0.014-in. guidewire for coronary recanalization, coronary guiding catheter (Judkins Right or Multipurpose), and coronary balloons. After the occlusion lesion was crossed through the arm approach with a 0.014-in. guidewire, predilatation with coronary balloon was performed to provide a channel for passing a 0.035-in. guidewire through the femoral approach. In cases of subintimal position of the guidewire, attempts were repeated until the central luminal passage was achieved. Recanalization was never performed subintimally. Predilatation was performed before stent placement using a peripheral balloon (diameter 7–10 mm).

In cases patients calcified lesions, angulation, or long lesions, which did not allow accurate stent positioning, the snare technique was used. The 0.035-in. guidewire used in femoral approach was always used to trap and withdraw the lesion through the brachial or the radial approach. If possible, stents were advanced through femoral approach. Angiographic control was performed immediately after stent deployment, and the gradient pressure was recorded. Technical success was defined as angiographic residual stenosis <20% and a gradient <5 mmHg across the treated lesion. Both self- and balloon-expanding stents were used. Stent and balloon diameters were determined according to the reference vessel diameter in the vicinity of the lesion. For balloon-expandable stents, a diameter equivalent to that of the reference vessel was selected, whereas for other self expanding-type stents, a diameter 1 mm larger than that of the reference vessel was chosen. Before using MSCT, the diameter of the target artery was estimated using quantitative computed angiography or, after angiography, by comparing the predilatation balloon size and dimension of the distal landing zone. More recently, MSCT (Fig. 3) was used for measurement of the target artery diameter. The degree of target artery calcification was estimated using digital subtraction angiography, duplex ultrasound scanning, and MSCT and graded as follows: none, mild, moderate, and severe.

Drug Administration

Acetylsalicylic acid (100 mg/d) and ticlopidine (250 mg bid) or clopidogrel (75 mg/d) were administered for >3 days before the procedure. After 2002, dual antiplatelet therapy was administered in all patients during 12 months after intervention and continued with acetylsalicylic acid. Patients experiencing side effects, such as bleeding, appetite loss, headache, or palpitation, were treated with a single agent. Other cardiovascular medications were used when clinically indicated.

Definitions

Clinical success was defined as a technical success with symptom resolution, whereas clinical failure was defined as a resumption of clinical symptoms with angiographic recurrence. The other end point was death (successful or failed recanalization). We defined primary patency as uninterrupted vessel patency without repeat intervention.

Follow-Up

The patients were seen by an attending surgeon at 1, 3, and 6 months during the first year and annually thereafter. Duplex ultrasound scanning in addition to symptoms and clinical examination (presence of a palpable radial and ulnar artery pulses) was performed in all of the patients. Indications for repeat intervention included recurrent symptoms, accompanied by recurrent stenosis >60%, as confirmed by duplex scan or arteriography.

Statistical Analysis

All data are expressed as means ± SDs. Chi-square and Student *t* tests were used for comparisons between the subgroups for categorical and continuous variables, respectively ($p < 0.05$ was considered significant). Kaplan–Meier curves were constructed to assess mortality and restenosis-free survival during the follow-up period. Univariate analysis was performed to assess the predictors of initially successful recanalization and long-term patency of the initially recanalized SA ($p < 0.1$ was considered significant).

Results

All occlusion lesions were located in the part of the SA proximal to the origin of the vertebral artery. Successful recanalization (Fig. 4) of the SA was achieved in 46 patients (82.1%), whereas percutaneous recanalization failed in 10 patients (17.9%) because of inability to cross the lesion with the wire despite combined femoral and arm approach. In two patients, additional simultaneous stenting procedures were successfully performed because of post-vertebral stenotic lesion. Baseline demographic characteristics of enrolled patients, with respect to the primary success of recanalization, are listed in Table 1.

There were no differences in sex, age, and other demographic data between patients with successful and failed percutaneous recanalization of the SA. Even symptoms did not differ between the groups. The most common presenting symptoms were vertebrobasilar insufficiency and arm claudication. The ipsilateral vertebral artery was patent in all of the patients, with antegrade flow in three patients and retrograde blood flow in the remaining patients, including five patients with stenotic lesion of the vertebral artery. These five patients (8.9%) received endovascular treatment in the same session, followed by ostial vertebral artery stenting in three of them. Table 2 lists the procedural data.

Table 1 Basic demographic data with respect to the primary success of recanalization

Variable	All patients ($N = 56$)	Success ($N = 46$)	Failure ($N = 10$)	p[a]
Male sex (%)	25 (44.6)	22 (47.8)	3 (10)	0.30
Age (y) (%)	58 ± 8	58 ± 8	56 ± 6	0.35
Hypertension (%)	41 (73.2)	34 (73.9)	7 (70)	0.80
HLP (%)	33 (58.9)	25 (54.3)	8 (80)	0.13
Diabetes mellitus (%)	19 (33.9)	14 (30.4)	5 (50)	0.24
Current smoking (%)	47 (83.9)	38 (82.6)	9 (90)	0.56
PAD (%)	15 (26.8)	12 (32.6)	3 (30)	0.80
CAD (%)	21 (37.5)	16 (34.7)	5 (50)	0.37
CVI (%)	11 (19.6)	10 (21.7)	1 (10)	0.39
Symptoms				0.70
VBI	18 (32.1)	13 (28.2)	5 (50)	
Claudication	13 (23.2)	11 (23.9)	2 (20)	
VBI + claudication	15 (26.0)	13 (28.2)	2 (20)	
Coronary ischemia	7 (12.5)	6 (13)	1 (10)	
Prep for CABG	3 (5.4)	3 (6.5)	0 (0)	

CVI cerebrovascular insult, *HLP* hyperlipoproteinemia, *CAD* coronary artery disease, *PAD* peripheral artery disease, *VBI* veretebrobasal insufficiency

[a] Difference between patients with successful and failed SA recanalization

Table 2 Procedural data with respect to primary success of recanalization

Variable	All patients ($N = 56$)	Success ($N = 46$)	Failure ($N = 10$)	p[a]
Length of occlusion(mm)	24.59 ± 7.38	24.04 ± 7.67	27.1 ± 5.52	0.24
Target artery calcification (%)				
None	2 (3.6)	2 (4.3)	0 (0)	0.50
Mild	15 (26.8)	13 (28.3)	2 (20)	0.59
Moderate	21 (37.4)	18 (39.1)	3 (30)	0.58
Severe	18 (32.1)	13 (28.3)	5 (50)	0.18
Approach (%)				0.09
Femoral	9 (16.1)	8 (17.3)	1 (10)	
Arm	6 (12.7)	3 (6.5)	3 (30)	
Both	41 (73.2)	35 (76.2)	6 (60)	
Side of occlusion (left) (%)	52 (92.9)	42 (85.7)	10 (100)	0.33
Stent type (%)				
No stent	10 (17.9)	N/A	10 (100)	
Self-expandable	17 (30.4)	17 (36.9)	N/A	
Balloon-expandable	29 (51.8)	29 (63.1)	N/A	
Mean stent diameter (mm)				
All stents		8.34 ± 0.83		
Self-expandable		8.27 ± 0.82		
Balloon-expandable		8.41 ± 0.85		
Stents per patient	0.93 ± 0.57	1.13 ± 0.40	N/A	
Complications (%)	4 (7.1)	4 (8.7)	0 (0)	0.13
Conversion to surgery (%)	9 (16.7)	0 (0)	9 (90)	<0.0001
In-hospital mortality (%)	0 (0)	0 (0)	0 (0)	1

[a] Difference between patients with successful and failed SA recanalization

Again, there were no differences between the groups with respect to length and side of occlusion, but there was a trend toward greater incidence of periprocedural complications and combined use of femoral and arm approach in patients with successful recanalization. Complications included hematoma at puncture site in two patients and transitory ischemic attack and peripheral embolism in one patient each. Patients with failed percutaneous recanalization were more frequently switched to subclavian bypass surgery. There were no deaths during the index hospitalization. There were no differences in success rate between the different approaches, except that the arm approach yielded a lower success rate compared with the combined (both femoral and radial) approach ($p = 0.03$). Average duration of follow-up for the whole group was 40 ± 26 months (range 2–125 months). During the follow-up period, restenosis occurred in 11 patients (23.6%) in whom primary recanalization was successful. Only 1 patient underwent redilatation of the SA, and 2 patients underwent SA bypass surgery during the follow-up period. Of the remaining 8 patients with restenosis of the SA, 6 were asymptomatic, 1 patient was scheduled for redo coronary artery bypass surgery (only vein grafts were used), and 1 patient refused reintervention on the SA. These patients were treated by exercise rehabilitation and drug therapy. A trend toward increased mortality (21.7% vs. 50%, $p = 0.07$) was noted in patients with failed recanalization of the SA (Table 3).

Figures 1 and 2 show Kaplan–Meier curves for mortality and presence of restenosis for all of the patients as well as those with successful recanalization, respectively. Univariate analysis evaluating the following factors failed to identify any variable predictive of successful SA recanalization: age; sex; risk factors for vascular disease; presence of cerebrovascular, cardiac, and peripheral artery diseases; length and side of the occlusion; and vascular access. Similarly, univariate analysis evaluating the type of stent used and periprocedural complications in addition to the above-mentioned variables failed to identify any variable predictive of long-term patency of successfully recanalized SA (Figs. 3, 4).

Discussion

Until the mid-1990s, surgery was the preferred approach for SA occlusive disease and had low complication rates and good long-term outcomes [20, 21]. In a study in 1996,

Table 3 Follow-up data with respect to primary success of recanalization

Variable	All patients ($N = 56$)	Success ($N = 46$)	Failure ($N = 10$)	p^a
Length of F/U (mo)	40 ± 26 (range 2–125)	41 ± 27 (range 2–125)	38 ± 23 (range 12–72)	0.41
Restenosis (%)				
1 year	1 (1.7)	1 (2.1)	N/A	
3 years	8 (14.2)	8 (17.3)	N/A	
End of F/U	11 (19.6)	11 (23.9)	N/A	
Mortality (%)				0.07
1 year	3 (5.3)	2 (2.1)	1 (10)	
3 years	10 (17.8)	7 (15.2)	3 (30)	
End of F/U	15 (26.7)	10 (21.7)	5 (50)	
Subclavian re-PTA	1 (1.7)	1 (2.1)	0 (0)	0.11
Subclavian bypass surgery	2 (3.5)	1 (2.1)	1 (10)	0.78

F/U follow-up

[a] Difference between patients with successful and failed SA recanalization

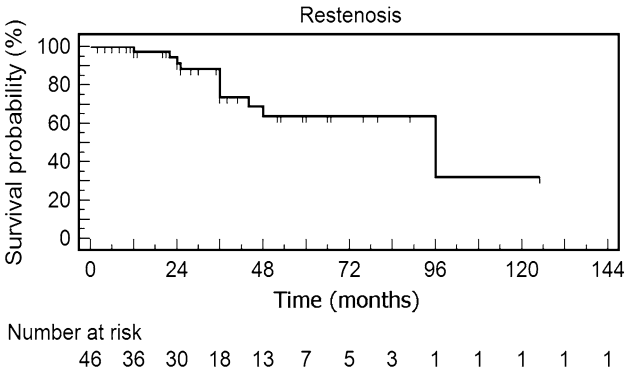

Fig. 1 Kaplan–Meier curves for presence of restenosis for the patients with successful recanalization

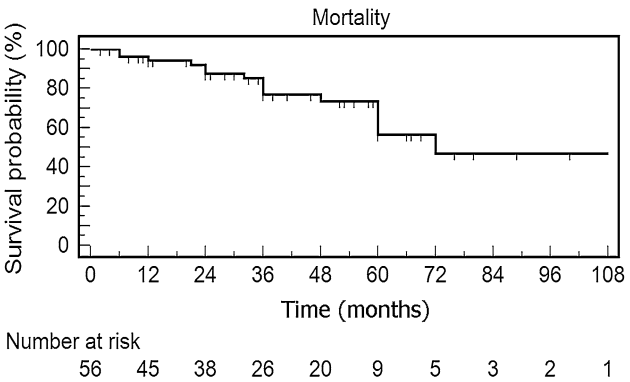

Fig. 2 Kaplan–Meier curves for mortality for the entire group of patients

Motarjemeet et al. [22] reported low procedural success rate (46%) of angioplasty in SA occlusions associated with poor long-term results: During 1-year follow-up, 50% of the successfully recanalized arteries developed recurrent steno sis. In using PTA alone for the treatment of SA occlusion, most series reported <50% patency at 4–88 months of follow-up [23, 24]. In recent years, the advent of new technology and new types of stents has extended the use of endovascular procedures to more extensive SA occlusive disease. Indications for treatment of CTO of the SA were previously mentioned. In our study, the most common indication for intervention was symptomatic subclavian steal phenomenon in 33 patients (58.1%). Thirteen patients (23.2%) had arm claudications, and 7 patients (12.5%) had coronary ischemia (internal thoracic artery was used for CABG). Three patients (5.4%) were treated for scheduled coronary bypass surgery using LITA graft. In our series, successful recanalization of the SA was achieved in 46 patients (82.1%). During follow-up (mean 40 ± 26 months [range 2–125]), primary patencies after 1 and 3 years were 97.9% and 82.7%, respectively. At the end of follow-up, 76% of the arteries had no evidence of restenosis. A combination of PTA and stenting was performed in all of the patients with successful recanalization, mostly using balloon-expandable stents ($n = 29$ [51.8%]). Balloon-expandable stents are preferred for ostial lesions because of the high accuracy of placement with respect to the aortic arch and vertebral artery and high radial force. In addition, they are ideal for short occlusions in which the artery is not curved. Self-expanding stents are preferred for longer occlusions or for occlusions distal to the origin of the vertebral artery. Most series [16, 18, 19, 25, 26] have reported predominantly using balloon-expandable stents for treatment of obstructed SA. Self-expanding stents are contraindicated for ostial lesion treatment because these devices may slip down into the aorta. However, Wang et al. reported [27] using self-expandable stents for all of the procedures and documented

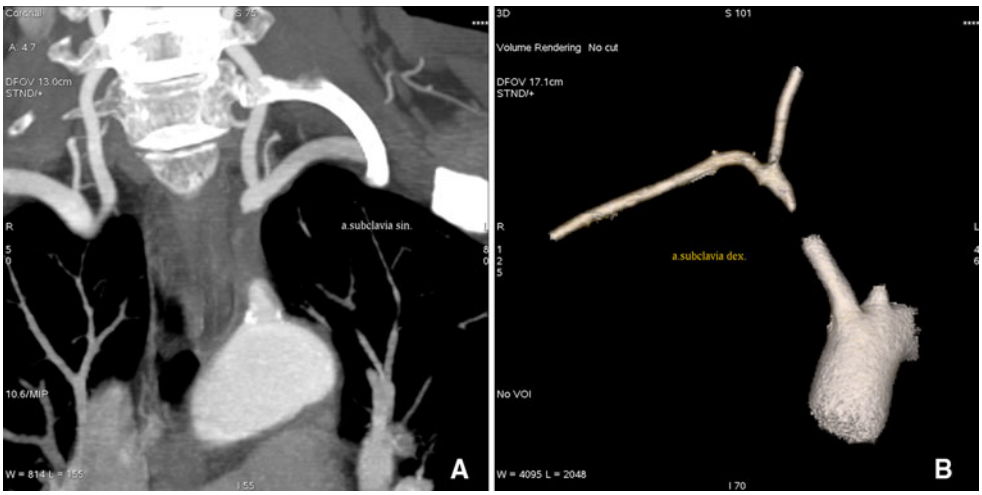

Fig. 3 MSCT showing CTO of the left (**A**) and right (**B**) SAs

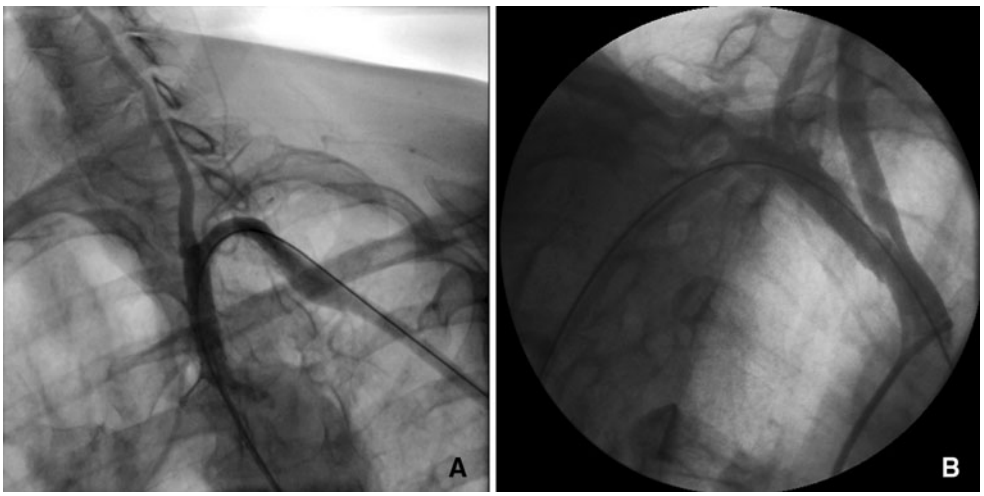

Fig. 4 Angiogram after successful recanalization and stent implantation of the **A** left SA and the **B** right SA

only one (1.7%) embolization of the left axillary artery by a broken tip of a stent delivery system. Different sheath sizes were used for the femoral and radial approaches because of differences in the diameters of these arteries and because of the possibility of radial artery thrombosis, which is more likely to occur if the larger sheath diameter is used. Rodriguez-Lopez et al. [9] reported a 5.7% brachial thrombosis rate caused by 7F sheaths that required open thrombectomy. Similarly, Sullivan et al. [4], using the femoral access 1.8 times more frequently than the brachial access, experienced five times more brachial artery than femoral artery complications.

All techniques yielded similar success rates, with the exception of the combined over-radial approach. The reasons for this are not clear, but the following may be operative: (1) a small number of patients spanned over a long time interval does not allow for this type of subanalysis, (2) the evolution of techniques over time, and (3) patient and lesion characteristics that influenced choice of technique.

De Vries et al. [18] reported that in mean follow-up of 34 months, 8 patients (7.9%) developed significant recurrent obstruction. However, none of these patients primarily had a SA occlusion ($n = 13$, 65% successful recanalization with 61% stenting procedures). In this series, the 5-year primary patency rate was 89%, with no significant difference between stented and nonstented arteries in terms of recurrent stenosis rate. Rodriguez-Lopez et al. [9] achieved technical success of PTA with stenting in 88% (15 of 17) CTO of the SA. During mean follow-up of 9 months, they had no Doppler or clinical evidence of restenosis. In this series, during follow-up >13 months (range 1–64), 7% were asymptomatic and 3% were symptomatic restenosis. In addition, they documented an 11% minor complication

rate and a 4% major complication rate, which included SA dissection, axillary artery thrombosis, brachial artery thrombosis, and transient ischemic attack on the day of the procedure.

Mathias [19] and Hebrang [28] reported >50% success rate with stenting for CTO of the SA. In contrast, Kumar et al. [29] reported a 100% initial success rate in 27 patients with CTO of the SA treated with primary stenting. Sixt et al. [30] reported stent-supporting angioplasty in SA occlusions associated with a high technical success rate (26 of 30 [87%]), with an 83% primary patency rate after 1 year.

There are number of surgical series dealing with the same or similar patient populations. Qi et al. [31] reported the result of 39 cases of axillo-axillary bypass grafting, 10 cases of carotid–subclavian bypass grafting, and 4 cases of ascending aorta-to-bisubclavian bypass grafting. In this series, initial success rate (98.11%) and long-term results were good; the graft patency rate was 100% at 1 and 2 years, but the complication rate in this series was 13.5%.

In a series of 51 patients with symptomatic SA disease (40 occlusions and 11 stenoses) treated with carotid–subclavian bypass, the investigators reported primary patency rates of 100%, 98%, 96%, and 92% after 1, 3, 5, and 10 years, respectively, with postoperative complication rates of 12% and a 30-day morbidity rate of 6% [32]. In a study of 108 patients with subclavian carotid transposition, Schardey et al. [33] found that overall patency after a mean observation period of 70 months (range 1–144) was 100%, with a complication rate of 15% and a morbidity rate of 3%.

Contrary to the surgical studies, the present study had a complication rate of 7.1% (4 of 56) and included hematoma at puncture site in two patients as well as TIA and peripheral embolism in one patient each. Of these, two complications required surgical treatment (one groin hematoma and one peripheral embolism). All four patients recovered fully.

In our study, during the follow-up period, stent failure occurred in 11 patients (23.6%). Significant recurrent stenosis (>75%) developed in 7 patients and recurrent occlusion in 4 patients. Henry [5] reported a stenosis rate of 16% after follow-up of 48 months, and Sullivan [4] reported a rate of 15% during 36 months of follow-up.

No predictors of restenosis were found in our study. Bates [2] found a greater trend toward recurrent stenosis in women ($p > 0.05$), but there were no other predictors of restenosis. A previous study [26] reported that low stent diameter, implantation of two stents, and hypertension were independent restenosis predictors. In addition, Schillinger et al. [34] found that long lesions and stent implantation were independently correlated with less favorable patency rates.

It would be of major clinical interest to improve the success rate of recanalization of CTO of the SA in the future, which can be achieved by the use of novel generations of guidewires specifically designed for this purpose and by careful selection of patients and recanalization technique based on lesion characteristics obtained through MSCT. To conclude, endovascular recanalization and stenting of the subclavian occlusive disease are safe and effective procedures associated with low risk and good long-term results.

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Conflict of interest None.

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