

CIRSE QUALITY ASSURANCE GUIDELINES FOR THE ENDOVASCULAR TREATMENT OF OCCLUSIVE LESIONS OF THE SUBCLAVIAN AND INNOMINATE ARTERIES

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Introduction

The innominate and subclavian arteries are the most common location of upper extremity artery disease. Nevertheless, symptomatic lesions of these arteries occur less frequently than symptomatic lesions of the carotid bifurcations. Only about 5% of patients with signs and symptoms of cerebrovascular disease present with subclavian steal syndrome and only 7% of these patients are symptomatic [1]. Symptomatic patients are typically younger patients than in ilio-femoral atherosclerotic disease with mean ages of 49 years to 69 years [2-5]. Subclavian or innominate artery stenosis is caused by a number of conditions with atherosclerosis being the most common cause followed by Takayasu's arteritis. Concomitant coronary artery disease is present in about 50% of the patients with innominate or subclavian artery occlusive lesions, peripheral vascular disease is present in 27% of the patients, and carotid and vertebral artery lesions are present in 29% of the patients [6-10]. These figures reflect the extent and severity of atherosclerotic vascular disease, with two thirds of the patient population having multiple supra-aortic and coronary lesions. Because of their comorbidity, these patients have a high surgical risk, which is responsible for the increased morbidity and mortality rates associated with surgical reconstructions.

In 1956 Davis et al. performed the first trans-thoracic innominate artery endarterectomy [11], and prosthetic bypass grafting was introduced by DeBakey and co-workers in 1958 [12]. Because of a considerably high operative mortality rate extra-anatomic procedures were developed. Extra-anatomic bypass grafts were reported to bring down the mortality rate from 22% with transthoracic repair to 5.6% with carotid-subclavian bypass grafting [13]. Percutaneous trans-luminal angioplasty

(PTA) of the aortic arch branches was introduced in 1980, and has subsequently evolved as an effective and safe treatment modality for occlusive lesions of the subclavian and innominate arteries. Stenting has been introduced for the management of the subclavian and innominate arterial occlusive lesions in the early 1990s to treat failures or complications of PTA, to increase the initial success of the recanalization of occlusions, to improve long-term patency, and to protect from atheromatous debris or thrombus dislodgement during PTA leading to cerebral embolization, by trapping this material between the vessel wall and the stent mesh [9,10,14-16]. Based on these improvements endovascular treatment became the preferred first line technique for the treatment of obstructive innominate/subclavian artery disease.

Definitions

- Clinical Symptoms

Innominate artery lesions may be asymptomatic. When symptomatic, patients present with neurological symptoms in a percentage ranging from 5% to 90%. Anterior cerebral circulation symptoms (right amaurosis fugax, right hemispheric transient ischemic attacks, stroke) are most common (50%) followed by vertebrobasilar symptoms in 40%, and both in 10% [17]. Upper extremity symptoms including either hand claudication, or finger embolization are present in up to 67% of the patients [6,7,18,19]. Combined upper extremity and neurologic symptoms occur in 32% to 38.5% of patients [17,20].

Patients with isolated subclavian artery lesions are often asymptomatic because of the presence of rich collateral supply. When symptomatic, the patients present with upper limb ischemia (muscle fatigue, "arm claudication", rest pain, digital necrosis from atheroembolization), ischemia of the posterior cerebral circulation (visual disturbances, vertigo, ataxia, syncope, dysphasia, dysarthria, sensory deficits of the face, and motor and sensory deficits of the extremities) or both. Patients with an internal mammary artery bypass may experience symptoms of myocardial ischemia.

- Lesion Classification

Lesions can be classified according to the Society of Interventional Radiology with technical success rate and potential long term outcome getting worse the higher the lesions category [21]:

Category 1: Stenotic lesions that are isolated, 3 cm or less in length, and with plaque that does not involve the right carotid artery, or either vertebral artery orifice.

Category 2: (a) Stenoses that are isolated, greater than 3 cm in length, and with plaque that does not involve the right carotid artery, or either vertebral artery orifice; (b) Stenoses dilated to provide

inflow to surgical grafts; and (c) Bypass grafts anastomotic stenoses in cases in which the risk of cerebral embolization is low.

Category 3: Short-segment occlusions (less than 5 cm) that often involve the origin of the subclavian and brachiocephalic arteries.

Category 4: Stenoses that involve the origin of the carotid and vertebral arteries or long-segment occlusions (greater than 5 cm).

- Primary Patency

Primary patency is defined as the uninterrupted vessel patency with no additional procedure performed on the treated segment [22].

- Secondary Patency

Secondary patency is defined as time from the procedure to the permanent loss of flow independent from any secondary intervention at the target lesion [22].

- Technical success

Technical success is defined as patency of the treated vessel (segment) with less than 20% residual stenosis depicted by post treatment digital subtraction angiography (DSA), without dissection or extravasation [21].

Pre-treatment Imaging

Diagnosis is established clinically and confirmed by means of Doppler ultrasound (DUS), computed tomography angiography (CTA), magnetic resonance angiography (MRA) or DSA. The goal of pre-interventional imaging is to localize the target lesion, evaluate its extension (involvement of common carotid or vertebral artery origin) and to assess the peripheral and intracranial run-off. Proximal intrathoracic lesion location makes DUS challenging and limits direct assessment or visualization of the lesion. Therefore contrast-enhanced CTA or MRA are considered the methods of choice for pre-interventional imaging. Both techniques are non-invasive and permit an excellent visualization of the supra-aortic vessels. Both techniques provide some information on plaque morphology and composition, with MR imaging being particularly suited for plaque imaging. Although it is commonly considered the diagnostic standard, invasive catheter arteriography is no more the method of choice and should be limited to cases where the diagnosis remains unclear. Nevertheless, a diagnostic arteriography needs to be performed immediately prior to a revascularization attempt.

Indications for Treatment

According to the guidelines of the Standards of Practice Committee of the Society of Interventional Radiology (SIR) the indications for treatment of the aortic arch vessel occlusive disease are controversial [21]. The complexity of the extracranial arteries and the presence of abundant collateral circulation make the clinical significance of a particular lesion difficult to predict. As a general rule, treatment should focus on symptomatic patients. An additional indication is the preservation of the inflow for planned surgical bypass, such as axillo-femoral, or left / right internal mammary-to coronary artery grafts (LIMA / RIMA). However, in the surgical series asymptomatic patients are also included. In these patients thrombus adjacent to the lesion is considered a contraindication because of the increased risk of brain embolization. However, early data indicates that the use of cerebral protection devices may help to overcome this limitation [23-25].

A) Innominate Artery

- 1) Neurological symptoms.
- 2) Vertebrobasilar ischemia.
- 3) Upper limb ischemia or digital embolization.
- 4) Prior to bypass procedures to cerebral, upper extremity, and lower extremity circulation.
- 5) Prior to ipsilateral carotid endarterectomy or stenting.
- 6) Angina in patients with RIMA graft.
- 7) Leg claudication in patients with axillo-femoral grafts.

B) Subclavian Artery

- 1) Vertebrobasilar ischemia.
- 2) Upper limb ischemia.
- 3) Angina in patients with LIMA graft.
- 4) Critical Limb Ischemia in patients with axillo-femoral grafts.
- 5) To improve arterial inflow prior to scheduled operative procedure.

Contraindications

Absolute contraindications include:

- Medically unstable patients.
- Thrombus adjacent to the lesion (asymptomatic patient).

Relative contraindications include:

- Thrombus adjacent to the lesion (symptomatic patients).
- Uncorrectable bleeding disorder.
- Impaired renal function (eGFR < 30 ml/min/1.73 m²).
- Pregnancy.
- History of severe allergic reaction to iodinated contrast media.
- Hypersensitivity to aspirin and/or clopidogrel.
- Inability of the patient to lay flat and immobile.
- Critically ill elderly patients with impaired mobility and dementia.

Patient Preparation

Physical examination needs to check for the above mentioned signs and symptoms. A baseline neurologic examination is recommended. In addition blood pressure measurements need to be obtained, with a difference of ≥ 15 mmHg being suspicious for unilateral subclavian or innominate artery stenosis. Auscultation beginning in the supraclavicular fossa is recommended. Absent subclavian pulses may indicate occlusion. Finger ulcers or skin changes may indicate atheroembolization from ulcerated lesions.

In cases of impaired renal function patients should be treated according to the current European Society of Urogenital Radiology (ESUR) guidelines [26]. Patients with known allergic reactions to contrast material should be prepared according to international guidelines [27]. The platelet count should be > 50.000 and INR < 1.5 , otherwise appropriate measures to correct the coagulation state have to be undertaken. Peripheral i.v. access must be obtained and the urinary bladder should be emptied before the initiation of the procedure.

Equipment Specifications

For subclavian and innominate artery revascularization a dedicated fix C-arm unit with a digital detector with a large field-of-view providing high quality imaging, road map or image overly options and sufficient magnification is strongly recommended.

Standard materials include:

- 4-5 Fr catheters, typically with Headhunter, JB1, MP or Sidewinder configuration and 0.035", 0.018" and 0.014" (hydrophilic) guide-wires

- Various semi-compliant balloons (diameter: 6-12 mm, length: 20-40mm) either in over-the-wire (OTW) or rapid exchange (Rx) technology. .
- Various 4-7F sheath with up to 90 cm length (0.035" guidewire compatible) for the transfemoral approach as well as micropuncture sets (0.018" guidewire compatible) for a transbrachial or transradial access.
- 8-12 mm stents with variable lengths (12-40mm). For treating ostial lesion balloon expandable stents should be available as they can be placed more precisely and have higher hoop strength. In self expandable stents, stent size should exceed the target vessel size by 1-2 mm, while it should fit the nominal vessel size if balloon-expandable stents are used.
- The availability of stent grafts and balloons for vessel occlusion is indispensable for the management of bleeding complications in the angio-suite.
- 6 F large lumen guide catheter (endhole thrombectomy catheters) and thrombolytic agents need to be available for the management of intra-procedural embolic complications. Microcatheters and stent retrievers to treat intracranial emboli should be on stock.

Procedural Features and Variations of the Technique(s)

A) Innominate Artery

Innominate artery lesions are best depicted in LAO projections. In the largest series of innominate artery endovascular treatment the femoral artery access was used. The axillary artery, and the brachial artery were used less frequently [4,8,14,28]. The brachial artery approach offers a better chance of crossing a complex lesion, but is associated with more access site complications: Rodriguez-Lopez et al reported a 5.7% brachial thrombosis rate caused by 7F sheaths requiring open thrombectomy [9]. Similarly Sullivan et al, using the femoral access 1.8 times more frequently than the brachial access, experienced 5 times more brachial artery than femoral artery complications [14]. Ultrasound-guided puncture, the use of micropuncture sets and new, low profile balloons (0.018" or 0.014" compatible), and stents may obviate this problem. Another method (enabling the use of smaller sheaths) is to cross the lesion from the ipsilateral brachial artery and snare the guidewire from the groin, in order to place the stent from the femoral approach [29].

Typically a long sheath is placed in the aortic arch, so that the lesion can be visualized by DSA or by road mapping. Alternatively a pigtail catheter placed from the contralateral femoral artery, or from the brachial artery serves the same purpose. Mostly balloons with diameters of 6 mm to 12 mm are used. In the past, stents were used for unsatisfactory PTA results, but nowadays primary stenting is the method of choice. Usually balloon expandable stents are used for short and/or ostial lesions. Care should be exercised to place the stent, so that it does not protrude more than 2 mm into the aorta, or into the orifice of the right carotid artery. No specific recommendation can be made regarding the situation of the bovine arch variation. In such a situation care should be taken not to stent across the origin of the left carotid artery.

Queral and Criado treated 8 innominate artery lesions with stent placement following surgical exposure of the ipsilateral common carotid artery; the stents were placed in a retrograde fashion. The cephalic part of common carotid artery was clamped for protection against embolization [8]. A similar approach has been used by Grego et al. [30], and by Allie et al. [31], for the treatment of innominate artery or common carotid artery lesions associated with tandem carotid bifurcation lesions in symptomatic patients. Excellent technical success rates without perioperative strokes were reported. Several recent reports indicate the feasibility and safety of cerebral protection devices in percutaneous innominate artery revascularization [23-25].

B) Subclavian Artery

The most preferred access artery for the treatment of stenotic lesions is the femoral artery, although the brachial, or the axillary artery has been routinely used by some operators [9]. The brachial approach, however, is associated with an increased rate of access artery thrombosis as described above [9,14]. With the introduction of ultrasound-guided puncture, micropuncture sets and modern low profile balloons and stent systems this problem may be obviated. The advantage of the brachial artery approach lies in the shorter and less tortuous path to the lesion resulting in a better pushability; this is important in the case of total occlusions, which are often impossible to cross from the groin, thus necessitating the brachial approach. Occasionally a through and through technique with transbrachial access for lesion crossing and transfemoral access for passing the stent may also be used in particularly difficult cases if the use of large reinforced sheaths is contraindicated. Only recently the transradial access was established as a safe alternative to the transbrachial approach [32]. Access via axillary artery should be avoided due to the relevant number of access related complications.

As it is true for the innominate artery lesions, primary stent placement is common practice in recent series. However, there is no prospective randomized trial proving the benefit of primary stenting[33], although a recent meta-analysis including studies with lower levels of evidence indicated an advantage of stenting over PTA alone [34]. Balloon expandable stents are more frequently used, but self- expanding stents are used especially in long (>40 mm) lesions [10,35]. There are anecdotic reports on the use of cutting/scoring balloons. It is recommended to avoid PTA or stenting across the vertebral artery origin, as it may increase the likelihood of vertebral artery occlusion, and/or brain embolization [35,36].

Medication and Peri-procedural Care

Although there is not enough evidence for this type of lesions pre-interventional antiplatelet therapy is strongly recommended. It should include clopidogrel (75 mg/day) and aspirin (100 mg/day) starting 3 days prior to the procedure. Alternatively clopidogrel can be administered with a loading dose of

300 mg. During the procedure, 3000-5000 IU of heparin are administered intra-arterially in order to maintain an activated clotting time (ACT) of 200 to 250 s.

During the procedure patients require continuous monitoring of vital signs including blood pressure, heart rate and oxygen saturation. In rare cases with vaso-vagal syndrome (hypotension, bradycardia and sweating) the need for atropine administration may occur.

Post-procedural Follow-up Care

Directly after the procedure and prior to discharge from hospital the local access site needs to be inspected. Distal pulses need to be checked, particularly if closure devices were used. Except for a completion angiogram no routine imaging is needed after the procedure. Clinical examination is usually sufficient to assess the treatment success. A consequent post-procedural antiplatelet therapy is needed with a double platelet therapy for as described above for about 6 weeks followed by life-long single antiplatelet therapy.

Follow-up should be performed in 6 months intervals, including blood pressure measurement at both arms and DUS. Further imaging studies are only recommended in symptomatic patients with CTA being the method of choice after stenting. MRA is only of limited use in the presence of stents due to susceptibility artifacts. The latter are likely to hamper assessment of in-stent restenosis.

Outcome

All published data of endovascular treatment are retrospective studies; there is no randomized study comparing percutaneous angioplasty (PTA) to stenting, or PTA/ stenting to surgery. Furthermore, many articles include innominate artery and subclavian artery lesions, thus complicating the interpretation of the results.

A) Innominate Artery

Surgical techniques for innominate artery lesions include direct reconstruction and extra-anatomic bypass. The former may be accomplished by endarterectomy, and aortic origin grafting. Extra-anatomic methods include subclavian-subclavian artery bypass, axillary-axillary artery bypass, or contralateral carotid-carotid artery bypass. The extra-anatomic methods were advocated to reduce the high morbidity and mortality rates associated early in the experience of the direct reconstructions [13]. Direct reconstruction is favored in most recent series. Direct reconstruction includes aortic origin bypass grafting and endarterectomy. Endarterectomy and aortic origin grafting

are equally effective: there is no difference in early or late failures following either of these two procedures [17]. Nevertheless, endarterectomy is indicated in selected patients with limited extent of the atherosclerotic disease. Involvement of the origin of the innominate artery by atheromatic process is a contraindication to endarterectomy as it precludes safe clamping [19]. The operators with the largest recent experience prefer the bypass technique for innominate artery lesions [6,7]. Immediate clinical success is reported in 95% of the patients, and long-term clinical success in 87% to 90% [13,17]. The two largest series of innominate artery bypass including 246 patients reported that the probability of freedom from stroke was 87% to 88.8% at 5 years, and 80.4% to 81% at 10 years. Primary graft patency was 94% to 98.4% at 5 years, and 88% to 96.3% at 10 years. Five-year survival ranged from 73% to 86%, while 10-year survival was 57% [6,7,18]. These excellent results are spoilt by peri-operative stroke and mortality rates of 5.4% to 8%.

Endovascular treatment is expected to reduce operative morbidity and mortality rates. Most reported series of endovascular treatment of innominate artery lesions include small numbers of patients [10,15,31,36]. The majority of these lesions are stenoses. There are only two series with more than 50 patients [4,37]. Technical success rates range from 83% to 96.6% [4,38]. Huttli et al. reported a clinical success rate of 93% [4]. Similarly good results were obtained in all other series. Perioperative deaths were not procedure related, but due to comorbidities [39]. However, major stroke and TIAs may occur [4]. Technical success is in general better in stenotic lesions with a technical success rate of about 100% when compared with total occlusions with technical success rates in the range of about 80% to 90% [40,41]. Very good short and long term patency rates are obtained. Paukovits reported primary and secondary patency rates of 98% and 100% at 24 months and Huttli et al. reported 93% and 98% primary and secondary patency rates at 10 years, respectively (Table 1) [4,37].

B) Subclavian Artery

Operative methods include carotid-subclavian bypass using synthetic grafts or saphenous vein, and transposition of the subclavian artery unto the common carotid artery. Perioperative mortality is low (0-0.8%), and stroke rate ranges from 0-5%. Five-year primary patency rates range from 92% to 95%, and eight to ten year primary patency from 83% to 95% [39,42,43]. Transposition of the subclavian artery has reportedly lower mortality and morbidity and better patency rates [42-44]. Nevertheless, a 1.4% mortality rate was reported [44]. Moreover, this method cannot be applied in case of 1) a proximal origin of the vertebral artery, 2) atheromatous involvement beyond the origin of the vertebral artery, and 3) a LIMA graft.

Technical success rates of endovascular treatment for stenosis reach up to 100% [3], while for occlusions the technical success is considerably lower with about 69-85.7 [36,45,40], although Martinez et al. reported 94% success rate in an earlier study [16]. Clinical success is achieved in most

technically successful cases. No perioperative deaths have been reported, while the stroke rate (TIAs included) ranges from 0.9% to 1.4%. In fact, only five cases with stroke were reported, while TIAs appear to be somewhat more common [36,45,46]. Major complications range from 0% to 8.5% (Table 2) [41,46]. These include access site hematomas, distal embolization, and arterial thrombosis especially of the brachial artery. These figures are better than those obtained by surgery, and justify the primary use of the endovascular techniques.

Mid-term patency is good with 88% - 97.9% at one year [40,41]. Again, results in stenoses were more favourable when compared with chronic occlusions. The only two studies reporting long term patency rates indicate an excellent durability of this technique with 10-year secondary patency rates of 84.5% and 92.6%, respectively [3,36]. Interestingly there were no more restenoses after 25 months. There are two studies comparing extra-anatomic bypass surgery and endovascular treatment. These data indicate a better mid-term patency for surgery, however, in one of these studies the technical success rate is unacceptable low and technical limitations may limit the value of these results (Table 3).

Nowadays primary stenting is applied in the majority of patients. However, there still is a controversy regarding this preference Schillinger, et al. reported four-year patency rates of 68% after PTA, and 59% after stenting ($p=0.02$). They concluded that stenting itself was an independent predictor for restenosis [5]. Bates, et al. using stents reported 72% five-year patency rate [2]. A ten year secondary patency rate 84.5% was reported by Henry et al; better patency was achieved using stents than with PTA alone: 67.5% versus 89.7% for primary patency, and 75.5% versus 96.9% for secondary patency ($p<0.001$) [36]. Schillinger et al. have identified the presence of long lesions, residual stenosis after PTA, and stenting as independent predictors for restenosis after successful intervention [5]. The experience of endovascular management of subclavian lesions in the setting of Takayasu's disease is limited. The largest number of patients with subclavian lesions is reported in three series (5 patients each). All of them conclude that the method is safe and effective [41,47,48].

Conclusions

Occlusive lesions of the innominate artery and the subclavian artery may cause serious morbidity and should be treated if symptomatic or to maintain inflow for other vascular bypass or shunt procedures. Endovascular treatment is recommended as a method of choice as these patients are mostly considered at high risk due to comorbidities. Although balloon angioplasty may be sufficient, stenting may provide better long term results and is mostly preferred over angioplasty. However, there is neither level 1 evidence to support stenting over angioplasty or surgical over endovascular treatment. Considering the low morbidity of endovascular therapy it should be the treatment of first choice for innominate artery and subclavian artery occlusive disease.

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APPENDIX

Table 1

Studies on Innominate artery angioplasty and stenting with more than 25 patients

Author	Year	Patients/ Lesions	Stents [n]	Technical Success	Complications		f/u [months]	mean restenosis	Primary patency	Secondary patency
					Minor	Major				
Huttl [4]	2002	89/89	1	96.6%	4.4	3.3	n.a.	3.4%	93%@117 mo	98%@117mo
van Hattum [38]	2007	30/30	20	83%	13.3	6.6	24 (1-94)	n.a.	79%@24 mo	n.a.
Paukovits [37]	2010	72/77	49	93.5%	6.4	1.3	42.3 (2-103)	6.5%	98%@24 mo	100@24mo

n.a. = not available

Table 2

Studies on subclavian artery angioplasty and stenting published within the last 5 years

Author	Year	Patients/ Lesions	Stents [n]	Technical success	Complications		f/u [months]	mean restenosis	Primary patency	Secondary patency
					Minor	Major				
Henry [36]	2007	237/n.a.*	164	94%	1.2%	1.2%	65.8	12%	78.1%@10ys	84.5%@10ys
Sakai [45]	2007	26/28	all	85.7%	11.5%	3.4%	n.a.	n.a.	n.a.	n.a.
Sixt [41]	2009	107/108	90	97%	2%	0%	29 (6-101)	9%	88%@12 mo	93%@12mo
Wang [46]	2010	59/61	all	95.1%	1.7%	8.5%	40.7 (1-119)	8.4%	82%@5ys	n.a.
Berger [3]	2011	81/n.a.	18	93%	3.7%	1.2%	82 (3-299)	34.6%	85.2%@10ys	92.6%@10ys
Babic [40]	2012	56/n.a.	all	82.1%	7.1%	0%	40 (2-125)	23.6%	97.9%@12mo	n.a.

n.a. = not available, mo = months; ys = years; * series includes 10 patients with innominate artery lesions

Table 3

Comparative studies on endovascular versus surgical therapy of subclavian artery lesions

Author	Year	Therapy	Patients/ Lesions	Stents [n]	Technical Success	Complications		f/u mean [months]	restenosis	Primary patency
						Minor	Major			
AbuRhama [49]	2007	OP	51	-	100%	0	5.9	92 (12-180)	n.a.	98%@3ys
		PTA	121	all	98%	9.2	5.9	41 (12-108)	n.a.	78%@3ys
Linni [50]	2008	OP	34	-	100%	0	11.7	52.6	n.a.	100%@5ys
		PTA	40	all	70%	5	0	50.1	n.a.	95%@5ys
Song 2012 [51]	2012	OP	104	-	99%	2.9%	6.7%	101	n.a.	95%@5ys
		PTA	148	all	97.3	4.1%	2%	67	n.a.	67%@5ys ¹

n.a. = not available, OP = extra-anatomic bypass; PTA = endovascular therapy; ys = years; ¹ = 86% secondary patency rate @ 5ys