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

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INCIDENCE

The innominate artery, the common carotid, and the subclavian artery are collectively named aortic arch arteries or brachiocephalic arteries.
Symptomatic lesions of these arteries occur less frequently than symptomatic lesions of the carotid bifurcations. The joint study of Arterial Occlusion reported that only 17% of lesions demonstrated on arteriography involved the innominate artery and the proximal subclavian arteries (1). In a large series including 1961 operations performed for cerebrovascular disease, only 7.5% involved the innominate, common carotid, or the subclavian arteries (2).
Innominate artery and subclavian artery occlusive disease occurs in relatively younger patients than commoner types of atherosclerotic disease. Mean age ranges from 49 years to 69 years (3-9). There is only slight predomination of male patients in most of the reports. In some of the reports female patients represent the majority (5,8,9).

ETIOLOGY

Atherosclerosis is the commonest cause. Takayasu's arteritis is the next most frequent cause although it is much less common. Radiation – induced atherosclerosis obliterans is a rare cause.

COMORBID CONDITIONS

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 (4,5,10-12). 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.

HISTORY

A patient with symptoms of subclavian artery occlusion was first reported by Savory in 1856 (13). In 1944, Martonell and Fabre reported a patient with occlusive disease of all great vessels, the so-called "Martonell syndrome" (14). Davis et al in 1956 performed the first trans-thoracic innominate artery endarterectomy (15), and prosthetic bypass grafting was introduced by DeBakey, et al. in 1958 (16). These operations were associated with a considerably high operative mortality rate. Because of these concerns extra-anatomic procedures were developed to reduce the operative risk. Diethrich, et al. analyzed the Houston group's experience with 125 cases of carotid-subclavian artery bypass grafts in 1967, thus popularizing this operation (17). Similarly, good results were reported by Crawford, et al. two years later: the mortality rate was reduced from 22% with transthoracic repair to 5.6% with carotid-subclavian bypass grafting (18).

Percutaneous transluminal angioplasty (PTA) of the aortic arch branches was introduced in 1980 by Mathias, et al. and Bachman and Kim, and has subsequently evolved as an effective and safe treatment modality for occlusive lesions of the subclavian and innominate arteries (19-31). 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 (7-12, 32-38).
According to the guidelines of the Standards of Practice Committee (SOP) of the Society of Interventional Radiology (SIR) the indications for treatment of the aortic arch vessel occlusive disease are controversial (39). 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, only symptomatic patients should be treated. An additional indication is the preservation of the inflow for planned surgical bypass, like axillo-femoral, or left internal mammary-to coronary artery grafts (LIMA). However, in the surgical series asymptomatic patients are also included.
All published data of endovascular treatment are retrospective studies; no randomized studies exist comparing percutaneous angioplasty (PTA) to stenting, or PTA/ stenting to surgery. Furthermore, the majority of these articles include innominate artery, subclavian artery, and common carotid artery lesions, thus complicating the interpretation of the results and the complications.

LESION CLASSIFICATION (39)

The SIR SOP document classifies the subclavian artery and innominate artery lesions into four categories:
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) By-pass 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).

DEFINITIONS

Technical success is defined as less than 20% residual stenosis depicted by post treatment digital subtraction angiography (DSA), without dissection or extravasation.
Hemodynamic success is defined as the absence of bilateral brachial blood pressure difference, and the availability of adequate inflow artery for the scheduled bypass procedure.
Clinical success is defined as the resolution of the symptoms.
Patency of the treated vessel (or segment) during follow up is better demonstrated by means of imaging such as DSA. The use of other imaging methods such as magnetic resonance angiography (MRA), or Color Doppler ultrasound are limited because of the presence of the metallic stent, or the deep location of the treated segment. The indirect methods recommended for the lower extremity arterial endovascular procedures, such as ankle-brachial index (ABI) measurements are not applicable for subclavian and innominate artery interventions (40). As a result many published reports use clinical criteria to evaluate the patency of the treated vessel.

Primary patency is defined as the uninterrupted vessel patency with no procedure performed on the treated segment.
Secondary patency is defined whenever maintenance of patency required a secondary intervention.

INNOMINATE ARTERY LESIONS

Innominate artery lesions are uncommon. These lesions represent only 1.7% of the 1961 operations performed at UCSF for occlusive lesions of the aortic branches, including the carotid bifurcations over 20 years (2).
Innominate artery lesions may be asymptomatic. When symptomatic, patients with innominate artery occlusive lesions present with neurological symptoms in a percentage ranging from 5% to 90% (3-5). In the Mayo Clinic series anterior cerebral circulation symptoms (right amaurosis fugax, right hemispheric transient ischemic attacks, stroke) were present in 50%, vertebrobasilar symptoms in 40%, and both in 10% (41). Upper extremity symptoms are present in 5% to 63.3% of the patients (3-5). These include either hand claudication, or finger embolization. Combined upper extremity and neurologic symptoms occurred in 32% to 38.5% in two recent surgical series (41,42). In the largest series of endovascular treatment of innominate artery lesions including 89 patients, 46 had vertebrobasilar insufficiency, 35 had upper limb claudication, and 17 had TIAs (6).

DIAGNOSIS

Physical examination is invaluable for the diagnosis. Cervical bruits indicate the presence of aortic arch vessel stenoses. Absent subclavian pulses indicate occlusion. Blood pressure difference in the arms is suggestive of unilateral occlusive disease of the innominate or subclavian arteries. Finger ulcers or skin changes may indicate atheroembolization from ulcerated lesions.
DSA of the aortic arch is the mainstay of the diagnosis. Contrast enhanced MRA has similar value.

SURGICAL TREATMENT

Surgery was advocated only in symptomatic patients. However, more recent surgical series include asymptomatic patients in a proportion ranging from 13% to 22% (4,5).
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 (18). Nevertheless these methods are associated with significant drawbacks: unfavorable patency rates (42); skin erosion and infection along the route of the graft crossing the trachea and the sternum; and interference with future coronary bypass grafting. Also the lesion remains in situ generating a persistent source of the athero-embolization.
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 (41). 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 (3). The operators with the largest recent experience prefer the bypass technique for innominate artery lesions (4,5).
Immediate clinical success is reported in 95% of the patients, and long-term clinical success in 87% to 90% (3, 18). 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 77.5%, while 10-year survival was 52% (4,5).
These excellent results are spoilt by peri-operative stroke and mortality rates of 5.4% to 8%. These disturbing numbers reflect the extent of the disease with multiple vessel involvement including the coronary circulation. Endovascular treatment is expected to reduce operative morbidity and mortality rates.

ENDOVASCULAR TREATMENT

INDICATIONS FOR ENDOVASCULAR TREATMENT (6,7,10,27,28,32,34)

a) Neurological symptoms (frequency 5%-90%), b) Upper limb ischemia or digital embolization (frequency 5%-64%), (c) Prior to bypass procedures to cerebral, upper extremity, and lower extremity circulation, (d) Prior to ipsilateral carotid endarterectomy.
It is recommended to avoid treatment of asymptomatic patients.

CONTRAINDICATIONS

Thrombus adjacent to the lesion is a contraindication because of the increased risk of brain embolization.

TECHNIQUE OF THE PROCEDURE

The innominate artery lesions are better depicted in LAO DSA 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 (6,7,10,27,28,32,34).
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. Balloons with diameters 8 mm to 12 mm have been used. In the past, stents were used for unsatisfactory PTA results, but more recently routine (primary) stenting is preferred. Usually balloon expandable stents are used for short lesions. Care should be exercised to place the stent, so that it does not protrude much 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.
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 (11). 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 (34). The use of new, lower profile balloons, and stents may obviate this problem. Another method (enabling the use of smaller sheaths) is to cross the lesion from the ipsilateral brachial or axillary artery and snare the guidewire from the groin, in order to place the stent from the femoral approach (37).
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 (10). A similar approach has been used by Grego, et al (43), and by Allie, et al (44), 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.
Heparin is administered during the procedure, and the patient receives antiplatelet regimen (aspirin) 100 mg/day to 325 mg/day, with or without clopidogrel 75 mg/ day) after the intervention.

RESULTS

Most reported series of endovascular treatment of innominate artery lesions include small numbers of patients (n=13 in ref 28, less than 11 in 6,7,10,12,27, 32, 34, 37, 43, 44). The only largest series includes 89 patients (6). The majority of these lesions are stenoses.
Technical success rates from 96.6% to 100% are reported. Clinical success was achieved in 93% of Huttl's, et al. patients. Similarly good results were obtained in all other series.
No perioperative deaths have been reported. Huttl, et al. reported one major stroke (1.1%) and 4% TIAs. Also 2% puncture site thrombosis was encountered that necessitated an operation.
Very good patency rates were obtained: Huttl, et al. report 93% and 98% primary and secondary patency rates at 10 years respectively. Allie, et al. obtained 100% patency rates at 34 months.

SUBCLAVIAN ARTERY LESIONS

Lesions of the subclavian arteries although infrequent are more common than lesions of other aortic arch branches. They involve 4.3% of the 1961 operations performed at UCSF for occlusive lesions of the aortic branches, including the carotid bifurcations over 20 years (2). The left subclavian artery is involved more often than the right. In a total of 124 subclavian artery lesions included in 4 subclavian artery stenting series, 107 (86.3%) were located on the left side (24, 29, 35, 36).
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, ischemia of the posterior cerebral circulation or both (7-9,11,12,21-38).
The radiographic subclavian artery steal alone as depicted by DSA or Duplex sonography has been disputed by vascular surgeons as a cause of neurological symptoms especially in the absence of concomitant extracranial occlusive lesions. It is rather considered a normal pattern of collateral response to proximal subclavian artery occlusion (45,46).
However, proximal lesions of the subclavian artery may be symptomatic in the presence of concomitant lesions. Concomitant carotid artery and vertebral artery disease in found in 29% to 85% of patients (1,12,18).
Those patients suffer from symptoms of vertebrobasilar insufficiency, such as visual disturbances, often bilateral, vertigo, ataxia, syncope, dysphasia, dysarthria, sensory deficits of the face, and motor and sensory deficits of the extremities.
Symptoms of the upper extremities include muscle fatigue, “arm claudication”, rest pain, and digital necrosis from atheroembolization.
Diagnosis is established by means of physical examination as described previously for the innominate artery, arch DSA, or MRA.

SURGICAL TREATMENT

Operative methods include carotid-subclavian bypass using synthetic grafts or saphenous vein, and transposition of the subclavian artery unto the common carotid artery (17, 47).
Carotid-subclavian bypass is accomplished using several conduits: PTFE grafts have the best patency, followed by Dacron grafts, and saphenous vein grafts. 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% (18, 48-50).
Tranposition of the subclavian artery has reportedly lower mortality and morbidity and better patency rates (50-52). Nevertheless, a 1.4% mortality rate was reported (51). This method cannot be applied in the following situations: a) Proximal origin of the vertebral artery, b) Atheromatous involvement beyond the origin of the vertebral artery, c) Presence of LIMA graft.

ENDOVASCULAR TREATMENT

Endovascular methods are attractive therapeutic alternatives because of the minimal invasive nature, and better patient tolerance.

INDICATIONS
Vertebrobasilar ischemia (23,24,28,30,31,34)
Upper limb ischemia, hand "claudication", digital embolization (7-9,11,12,21-38).
Both (11, 12, 24, 35).
Angina in patients with LIMA graft (7,12,33,34,36,38).
Leg claudication in patients with axillo-femoral grafts (12, 34, 35)
To increase inflow for scheduled operative procedure, ie LIMA graft, axillo-femoral graft, dialysis graft (11, 12, 34).

CONTRAINDICATIONS
The same as for innominate artery lesions.

TECHNIQUE

The procedure is performed with local anesthesia, under conscious sedation. Rodriguez-Lopez, et al. used general anesthesia in 59.4% of their patients, but most operators prefer local anesthesia (11).
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 (11). The brachial approach is associated with increased access artery thrombosis rates (11, 34), because of the small vessel caliber. With the introduction of 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; this is important in the case of total occlusions, which are often impossible to cross from the groin, thus necessitating the brachial approach (29, 35).
As it is true for the innominate artery lesions, primary stent placement is practiced in the most recent series. However, there is no study proving the benefit of using stents as a primary treatment.
Balloon expandable stents are more frequently used, but self- expanding stents are used especially in long (>40 mm) lesions (12, 29, 36). It is recommended to avoid stenting across the vertebral artery origin, as it may increase the likelihood of vertebral artery occlusion, and/or brain embolization (7, 29).
Like in the case of innominate artery PTA and stenting uncomplicated patients are discharged on antiplatelet regimen only.

RESULTS

Technical success rates of endovascular treatment for stenoses, in the most recent series, range from 91% to 100% (7-9, 11,12, 28, 33, 34). For occlusions the technical success is considerably lower ranging from 25% (36) to 83% (29), although Martinez, et al. reported 94% success rate (35). 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% (7-9,11,12,21-38). In fact, only one major stroke was reported by Henry, all the remaining were TIAs. These figures are better than those obtained by surgery, and justify the enthusiastic use of the endovascular techniques.

Major complications range from 0% to 10% (7, 11, 29, 31, 34). These include access site hematomas, distal embolization, and arterial thrombosis especially of the brachial artery.

Patency is comparable with surgery, although randomized comparisons with surgery have not as yet been published. Short –term patency is excellent: Two-year patency rates of 91% -92% have been reported (9, 11, 12). Martinez, et al. reported patency rates of 81% at 18 months for total occlusions (35). Long-term patency for endovascular treatment is inferior compared with the reported patency rates of surgery.
Schillinger, et al. reported four-year patency rates of 68% after PTA, and 59% after stenting. They concluded that stenting itself was independent predictor for restenosis (8). Bates, et al. using stents reported 72% five-year patency rate (9). Eight year patency rate of 87% (90% secondary patency) was reported by Henry et al; at 2.5 years, better patency was achieved using stents than with PTA alone: 87% versus 81% for primary patency, and 87% versus 94% for secondary patency. These differences did not achieve statistical significance (7).Schillinger, et al. have identified the presence of long lesions, residual stenosis after PTA, and stenting as independent predictors for restenosis after successful intervention (8). Bates et al found no clear predictors: however, they noted a higher trend toward recurrence in women (18.5% in female versus 8.6% in male) (9).
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 two small series (5 patients each). Both conclude that the method is safe and effective (53,54).

SUMMARY

Occlusive lesions of the innominate artery and the subclavian artery may cause serious morbidity and should be treated if symptomatic. Symptoms include neurological symptoms from the anterior or the posterior circulation, and/or upper limb ischemia. An additional indication is the maintenance of inflow for other vascular bypass procedures. Serious vascular comorbidity is usual in patients with innominate artery and subclavian artery atherosclerotic disease.
Endovascular treatment is recommended because they have lower complication rates compared with surgical methods. Although balloon angioplasty may be sufficient, stenting is most frequently used, although there is no level one evidence to support the use of stents over angioplasty. Excellent technical and clinical results are obtained with minimal morbidity and mortality. Although long-term patency rates may be inferior to those of surgical procedures, the minimally invasive endovascular treatment is the first choice treatment for innominate artery and subclavian artery occlusive disease.

Appendix 1: Evidence Table: Subclavian Angioplasty and Stenting

Author (ref)	**Year**	**study**	**Patients/Lesions**	**Stents**	**Tech success**	**Minor comp**	**Major comp**	**30-day-death+stroke**	**f-u mean (range)**	**restenosis**	**Primary patency**	**2nd patency**	**Survival**
Erbstein (21)	1988	retrospective	24/24	no	88%		1 bracha occl	0	(18-26 mo)	14.2%	na	na	na
Theron (22)	1985	retrospective	42/42	no	100%	na	na	0	na	na	na	na	na
Motarjeme (23)	1985	retrospective	22/22	no	73%	na	na	0	5 y	0	na	na	na
Wilms (24)	1987	retrospective	22/23	no	91%	0	1 axil a occl+1 digit embo	0	25mo	14%	na	na	na
Burke (26)	1987	retrospective	27/30	no	93%	1 digit embo	0	1 left stroke	37mo	0	na	na	na
Mathias (29)	1993	retrospective	46/46	7 Wall	83%	0	0	0	33mo	16%	87%@33 mo	na	na
Hebrang (30)	1991	retrospective	52/52	0	86.5%	0	0	0	29mo (6-48)	8.9%	78.8%@ 48 mo	na	na
Dorros (31)	1990	retrospective	27/30	0	100%	0	0	0	28mo (2-73)	13.6%	95%@28 mo		
Kumar (33)	1995	retrospective	27/31	All palmaz		2 Brach a repairs	0	0	na	na	na	na	na
Sullivan (34)	1998	Prospective registry-retrospective review	66/66	Palmaz+1 Wall	93.9%	3 brach a hemo	3 site requiring OR	0	14.3mo (1-49)	4.5%	84%@35 mo	na	na
Rodriguez-Lopez (11)	1999	retrospective	69/70	Palmaz+8 wall	96%		4,2% axil thromb, 5.7% brach thromb	1 TIA	13mo (1-64)	10%	92%@18 mo	96%@18m	na
Al-Mubarak (36)	1999	retrospective	38/38	31Palmaz +6 Wall	92%	0	0	0	20mo	6%	91%@20 mo	na	na
Henry (7)	1999	retrospective	113/113	Palmaz in 46 pts	91%		2.6%	0.9%	4.3y (-10y)	15.5%	83%@8y	90%@8 y	na
Brountzos (12)	2004	retrospective	39/39	Palmaz	94.9%	2 hemo	0	2 unrelated deaths	12.3mo (0.3-68.2)	10.8%	77%@24 mo	91.7%@ 24mo	na
Bates (9)	2004	retrospective	91/101	All	97%	14.3%	0	1 unrelated death	36.1mo (-109.5mo)		72%@5y		76%@5 y
Schillinger (8)	2001	retrospective	115/115	23% Palmaz	85%	na	na	na	na	na	59%@4y	na	na

Studies with > 20 patients with subclavian lesions are included
Pts=patients; Axil= axillary; Brach= brachial; Occl=occlusion; embo= embolization; hemo= hematoma; TIA= transient ischemic attact; OR=operative repair; y=year; mo=months, na=not available; Wall= Wallstents;@=at;

Table 2: Innominate artery angioplasty and stenting

Author (ref)	**Year**	**study**	**Patients/Lesions**	**Stents**	**Tech success**	**Minor comp**	**Major comp**	**30-day-death+stroke**	**f-u mean (range)**	**restenosis**	**Primary patency**	**2nd patency**	**Survival**
Huttl (6)	2002	retrospective	89/89	1	96.4%		2%puncture site thromb+ 4% TIAs	2%	na	3.4%	93%@117 mo	98%@117mo	Na
Motarjeme (28)	1999	retrospective	13/13	0	100%				5y	0	na	na	na
Allie (44)	2004	retrospective	11/11	11	97%				34mo	0	100%@34 mo	na	na
Brountzos (12)	2004	retrospective	10/10	10	100%		1 brach a embo+ 1TIA	0	12.3mo (0.3-68.2)	10%	na	na	na

Included only studies with > 10 patients with innominate artery lesions
Pts=patients; Axil= axillary; Brach= brachial; Occl=occlusion; embo= embolization; hemo= hematoma; TIA= transient ischemic attact; OR=operative repair; y=year; mo=months, na=not available; Wall= Wallstents,;@=at;

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