



## **CAR Standards for Percutaneous Transluminal Angioplasty**

*The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.*

Rapid and explosive growth in the application of Percutaneous Transluminal Angioplasty (PTA) has made developing up to date standards of practice for angioplasty a difficult task. The following standards which are mostly based on preliminary guidelines established by SCVIR for PTA in 1990, 1990, 1991 and 1992 are meant to be only guidelines to define in a general way the current standard of care and should not be used to discourage innovations or new developments in properly controlled clinical research protocols. For any given patient, alternative treatment may be valid or preferred for sound clinical reasons. In addition, certain procedures (surgical or interventional) require that the individual be highly trained in the specific technique. Practitioners are cautioned to recognize their own level of skill and experience, and to weigh the appropriateness of their interventions in that light.

### **1. DEFINITION**

For the purpose of these standards, Percutaneous Transluminal Angioplasty (PTA) is defined as a percutaneous transluminal balloon dilatation procedure. This procedure would generally involve percutaneous vascular access, transluminal passage of a balloon catheter, and treatment of the appropriate site(s) of stenosis by inflating the balloon. The angioplasty procedure also includes angiographic and hemodynamic documentation of the result of treatment.

### **2. DETERMINANTS OF SUCCESS**

A successful PTA procedure has two components: technical success (ability to correct stenosis or occlusion), and clinical success (ability to relieve symptoms).

The technical success is directly related to the features of the lesion treated, specifically its length, its morphology, whether it is a stenosis or an occlusion, concentric or eccentric, and its location in relation to the branching point. It also depends on the pathologic features of the lesion. Fibromuscular lesions are associated with a higher success rate than atherosclerotic lesions and atherosclerotic lesions are easier to dilate than myointimal hyperplasia associated with vein graft stenosis.

The clinical success depends on technical success, but also depends on the type of the lesion and the overall extent of the lesion. The extent of the lesion may be the most important determinant. Clinical success is highest when minimal disease is present elsewhere in the vascular tree.

### **3. DETERMINANTS OF PATENCY**

The duration of symptomatic improvement following a successful PTA depends on the vascular distribution of the lesion, the extent of the vascular disease and the control of the risk factors such as smoking. Generally, lesions that are short or located in large vessels, and cases in which there is minimal vascular disease elsewhere have a better patency rate. Repeat PTA of restenoses will extend the patency period, and should be considered when comparing long term patency rates between conventional surgical and percutaneous therapies.

### **4. LESION CATEGORIES**

Ideal lesions are those for which PTA is the procedure of choice because of a known association with high technical and clinical success rate and complete relief of symptoms.

Indicated but not ideal lesions are those which are well suited for PTA and for which significant relief of symptoms could be expected. This category includes lesions treated with PTA that will be followed by surgical bypass graft.

Infrequently indicated lesions are lesions that are amenable to PTA, but because of disease extent or location or severity a surgical bypass may be more suitable. However, PTA may be performed, generally because of patient risk factors or because of lack of suitable bypass material.

Lesions best avoided are lesions found with extensive vascular disease. Percutaneous treatment has a very limited role. It should only be considered as a last resort after weighing the risks versus possible benefits.

Contraindicated: The procedure should not be attempted.

## **A. SPECIFIC VASCULAR LESIONS**

### **1. Brachiocephalic Angioplasty**

PTA in brachiocephalic arteries is controversial. Carotid endarterectomy has a very low morbidity, but more complex surgical revascularization may be associated with 5% -10% mortality and a serious complication rate of 15% - 25%.

Published series on brachiocephalic angioplasty are small, but indicate a technical success rate of 88% and a complication rate of 5% in 182 procedures. Long term clinical success is reported in 46 patients and the patency rate is about 80% with two year follow up.

The most common indications have been subclavian steal syndrome, with symptoms of vertebrobasilar ischemia (gait disturbance, vertigo, or amaurosis fugax) or severe arm claudication or a combination of these. Symptomatic lesions with difficult surgical access such as stenoses at the origin of common carotid arteries are also suitable for balloon angioplasty if done with surgical exposure of the distal artery to control the debris. A secondary indication is to enhance inflow to the extra anatomic grafts, such as internal mammary-coronary artery graft.

#### a. Lesion category

1. Ideal lesions: brachiocephalic stenoses 3cm or less in length away from the origin of the carotid or vertebral arteries.

2. Indicated but not ideal:

(a) brachiocephalic stenoses greater than 3cm in length away from the origin of carotid or vertebral arteries

(b) carotid artery lesions with difficult surgical access when done with surgical exposure of the vessel for debris control

3. Infrequently indicated lesions: Short segment occlusions of the proximal brachiocephalic arteries.

4. Lesions best avoided:

(a) occlusions of brachiocephalic arteries > 5cm in length

(b) stenotic lesions in brachiocephalic arteries involving the origin of the vertebral or carotid arteries

5. Contraindicated : carotid or vertebral artery occlusions.

## 2. Renal Angioplasty

Renal artery stenosis and essential hypertension are both common in the adult population but less than 4% of hypertensives have a renovascular basis for their disease. In the absence of any standard algorithm for screening of the hypertensive population, diagnosing this subgroup is often not easy.

Indication for renal angioplasty: discovery of a hemodynamically significant renal artery stenosis in a patient with sudden onset or worsening of hypertension, or in a young patient with diastolic hypertension who responds only to drugs that block the renin-angiotensin system constitute the most common indication for renal angioplasty. The second group who may benefit from renal artery angioplasty are patients with worsening renal function and a concomitant decrease in renal size of one or both kidneys.

### a. Lesion Category

1. Ideal lesions: Fibromuscular renal artery disease. Renal artery transplant stenosis, and atherosclerotic lesions that are unilateral, shorter than 3cm in length and away from the renal artery ostium.
2. Indicated but not ideal lesions: Stenotic lesions involving renal artery ostia, atherosclerotic bilateral nonostial lesions, post operative anastomotic lesions and stenoses associated with moderate renal failure (creatinine < 265 mL/L).
3. Infrequently indicated lesions: Non atheromatous lesions such as Takayasu or neurofibromatosis, stenosis associated with severe renal failure for whom dialysis is imminent, and cases of renal artery occlusion.
4. Lesions best avoided: renal artery stenoses in patients with aortic aneurysm or severe aortic atherosclerosis.
5. Contraindicated: lesions associated with renal artery aneurysm.

## 3. Visceral Angioplasty

In the vast majority of cases, the stenoses or occlusions of chronic mesenteric ischemia are due to atherosclerosis. However, other disorders such as fibromuscular dysplasia, pseudoxanthoma elasticum, and a variety of arteritis, infiltrative disorders and malignant tumors are capable of producing vascular narrowing. Generally, stenosis in two visceral arteries must be present before the patient will have symptoms that warrant angioplasty.

The time tested treatments of chronic mesenteric ischemia have been surgical. The clinical outcome in reported cases of PTA in chronic mesenteric ischemia has been less than satisfactory. It may be reserved for patients with coronary morbidity and patients who have poor surgical risks.

### a. Lesion Category

1. Ideal lesions: There are no lesions for which angioplasty is clearly the procedure of choice, as there are too few patients reported in the literature to support that conclusion. This may however change as experience increases.
2. Indicated but not ideal lesions: Short segment < 3cm atherosclerotic or fibromuscular stenoses of the celiac and superior mesenteric arteries that do not involve the origin.
3. Infrequently indicated lesions: Ostial lesions or longer (> 3cm ) nonostial lesions of the celiac and superior mesenteric arteries.
4. Lesions best avoided: visceral artery occlusions, inferior mesenteric artery lesions and lesions in patients with clinical evidence of acute mesenteric ischemia.

5. Contraindicated: Arcuate ligament compression of the celiac artery.

#### 4. Aortic Angioplasty

Percutaneous angioplasty of severe focal lesions in the infrarenal abdominal aorta has been performed with excellent results. Treatment of diffuse lesions however has not been advocated. Discovery of severe focal aortic stenosis in patients with claudication of legs or buttocks constitutes an indication for therapeutic intervention. Many patients may also have impotence.

##### a. Lesion Category

1. Ideal lesion: short segment (< 2cm) stenoses of infrarenal aorta with minimal atherosclerotic disease of aorta otherwise.

2. Indicated but not ideal: medium length (2-4 cm) stenoses of infrarenal aorta with mild disease of the aorta otherwise.

3. Infrequently indicated lesions:

(a) long segment (> 4cm ) stenoses of infrarenal aorta

(b) aortic stenosis with atheroembolic disease (blue toe syndrome) or

(c) medium length stenoses (2-4 cm) of infrarenal aorta with moderate to severe atherosclerosis of aorta otherwise.

4. Lesions best avoided: aortic occlusion and aortic stenoses associated with abdominal aortic aneurysm.

#### 5. Iliac Angioplasty

PTA has proved to be an effective technique for treatment of symptomatic arteriosclerotic disease in the iliac arteries. A patency rate at 3-5 years of 80%-85% for ideal short segment lesions can be expected. The patency rate decreases to 75% for very difficult lesions. Although longer lesions can be successfully dilated, the long term patency is lower and surgical treatment would be preferred in such lesions if the patients have low surgical risk factors.

The presence of hemodynamically significant stenosis in patients with claudication that limits performance of daily activities , ischemic rest pain, gangrene, ischemic ulceration or tissue loss, or atheroembolism( blue toe syndrome) constitutes an indication for therapeutic intervention.

##### a. Lesion Category:

1. Ideal lesions: stenotic lesions less than 3cm in length that are concentric and non calcified.

2. Indicated but not ideal lesions: stenotic lesions 3-5 cm in length or shorter lesions that are eccentric or calcified.

3. Infrequently indicated lesions: stenotic lesions that are 5-10 cm in length or chronic occlusions less than 5cm in length after thrombolytic therapy.

4. Lesions best avoided:

(a) stenoses greater than 10 cm in length

(b) chronic occlusions longer than 5 cm after thrombolytic therapy

- (c) extensive bilateral atherosclerotic disease
  - (d) iliac stenoses in patient with abdominal aortic aneurysm or other lesions requiring aortic or iliac surgery
  - (e) total occlusion of an iliac artery which may benefit from thrombolytic therapy before PTA.
5. Contraindicated: Angiographic evidence of fresh thrombus. In these cases thrombolytic therapy may be appropriately followed by PTA.

## 6. Femoropopliteal Angioplasty

The indications for the treatment of femoropopliteal arteries by PTA are similar to those of iliac vessels. The success rate and patency rate overwhelmingly depend upon the characteristic of the lesion treated.

### A. Lesion Category:

1. Ideal: single stenoses or occlusions, up to 3 cm in length that are not at the proximal end of SFA or distal end of popliteal artery.
2. Indicated but not ideal lesions:
  - (a) single stenoses or occlusions, 3-10 cm in length, not involving distal popliteal artery
  - (b) heavily calcified stenoses up to 3 cm in length
  - (c) multiple stenoses and/or occlusions each less than 3 cm
  - (d) single or multiple lesions in blind popliteal artery to improve flow for distal surgical bypass.
3. Infrequently indicated lesions:
  - (a) single lesions involving distal popliteal artery
  - (b) multiple heavily calcified focal lesions
  - (c) single stenoses or occlusions with a length greater than 10 cm
4. Lesions best avoided: Complete common and/or SFA occlusions or complete popliteal and proximal trifurcation occlusions.
5. Contraindicated: Vessels with acute ischemic symptoms and angiographic evidence of fresh thrombus. Fibrinolytic therapy might benefit these patients.

## 7. Infrapopliteal Angioplasty

The new catheter and guide wire technology have allowed safe and efficacious application of angioplasty techniques to the infrapopliteal vessels. However the risks are somewhat greater and the indications are more limited. The procedure is only indicated in patients with severe symptoms such as ischemic rest pain, ischemic ulceration, or gangrene.

### a. Lesion Category:

1. Ideal lesions: single focal (< 1 cm) stenoses of tibial or peroneal vessels.
2. Indicated but not ideal lesions: multiple focal (1 cm) stenoses of tibial or peroneal arteries.

3. Infrequently indicated lesions: stenoses 1-4 cm in length or occlusions 1-2 cm in length.
4. Lesions best avoided: diffusely diseased tibial or peroneal arteries or longer than 2cm occlusions of these vessels.
5. Contraindicated: Lesions with angiographic evidence of fresh thrombus. Thrombolytic therapy might benefit these patients.

## **8. Angioplasty of Bypass Grafts**

Balloon angioplasty is a safe and effective means of treating stenoses that develop in or near bypass grafts. The patients may present with acute graft thrombosis with the underlying stenosis discovered only after thrombolytic therapy. A second group are asymptomatic patients whose lesions are discovered at routine follow up by diminished pulses or by non invasive vascular testing. The most common cause of stenosis in the grafts is myointimal hyperplasia which usually occur within the first year and occasionally later. Graft failure or occlusion in the week following operation usually indicates a technical problem and should be retreated surgically.

### **a. Lesion Category:**

1. Ideal lesions: focal stenoses in the distal end of the graft including aortorenal graft.
2. Indicated but not ideal lesions:
  - a) focal stenoses of the proximal anastomosis
  - b) short segmental stenoses occurring within vein bypasses
  - c) stenoses associated with aorto biiliac or bifemoral grafts
  - d) stenoses associated with prosthetic extraanatomic bypasses.
3. Infrequently indicated lesions: Vein bypass stenoses greater than 5 cm in length.
4. Lesions best avoided: Vein bypass stenoses greater than 10 cm in length and stenoses associated with anastomotic aneurysms.
5. Contraindicated: Graft failure or occlusion in the week following operation.

## **5. CREDENTIALLING CRITERIA FOR PERIPHERAL, RENAL, VISCERAL, AND AORTIC PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY**

### **A. THE PHYSICIAN**

That Physicians involved in the performance, supervision and interpretation of PTCA should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are foreign Specialist qualifications if the Radiologist so qualified holds an appointment in Radiology with a Canadian University.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

### **B. THE ANGIOGRAPHY FACILITY**

The angiographic examination required to assess a patient's suitability for PTA or post PTA results should be equal in quality to that required for diagnostic angiography performed prior to vascular surgery. The angiography facility should have the following:

- (a) a film changer capable of producing rapid serial images of at least 14 inches in diameter or a digital acquisition system with high spatial resolution and hard copy capabilities. The use of cineradiography is not recommended for the routine recording of noncoronary angiographic studies due to its unacceptably high patient- and operator- radiation dose
- (b) high resolution image intensifier and television chain
- (c) physiologic monitoring devices including those for BP and pulse oximetry and measurement of intraarterial pressures
- (d) facilities to treat and resuscitate patients in unstable condition
- (e) personnel trained to provide proper patient care and operation of the equipment.

### **C. SURGICAL SUPPORT**

A strong cooperative effort between the physician performing the procedure and a vascular surgery team is mandatory to ensure prompt institution of an operative repair should the need for one arise.

## **6. STANDARD FOR PROCEDURAL CARE FOR PTA**

### **A. Pre-Procedural Care**

Prior to any PTA the following documentation should be made:

1. A written medical history including a history of presenting symptoms, indications for the procedure, pertinent medical and surgical history, a list of current medications, allergic history and vascular risk factors.
2. Pertinent physical examination including a detailed vascular examination.
3. Complete diagnostic arteriography, permanently recorded, preferably on 14 inch or larger radiographs. This study may immediately precede intervention when appropriate.
4. Alternative form of treatment including surgical revascularization, should be discussed with the patient and referring physician.
5. Informed consent should be obtained in all cases.

### **B. Intraprocedural Care**

1. All patients should have intermittent BP and pulse monitoring.
2. All patients should have intravenous access.
3. If the patient is to be sedated, pulse oximetry should be used. A registered nurse whose primary responsibility is to monitor the patient should be present throughout the procedure.
4. The use of intraarterial pressure measurement is encouraged to assess the pre and post dilatation pressure gradient.
5. In all cases, post procedural arteriography should be performed and permanently recorded to document the anatomic result and to identify potential complications.

### **C. Post-Procedural Care**

1. Most patients will require a minimum of 6 hours of post PTA bed rest. This period could be reduced with the use of 5 F balloon catheters or application of a portable external compression device (Colapinto strap).

2. All patients should be observed in the postprocedural period by skilled nurses or other trained professionals, and monitored periodically for the status of the puncture site and vascular distribution distal to the puncture and the PTA site. Depending on the risk factors, observation period of up to 24 hours may be required.

3. Hemodynamic monitoring to detect delayed rupture and hemorrhage should be available

4. The initial ambulation of the patient must be supervised. Vascular perfusion, mobility, puncture site stability, and independent function must be assured.

5. In patients who have undergone renal angioplasty, close monitoring of blood pressure is important during the initial 24 hours. Intravenous access should be maintained for fluid resuscitation as needed.

6. Neurologic status should be assessed periodically following brachiocephalic PTA.

7. Travel time to a hospital should be less than 1 hour from where the patient is to spend the first night after the procedure.

### **D. Criteria for Short Term Observations**

#### **E. Contraindications for short-term observation**

Patients who have undergone renal, visceral, aortic or brachiocephalic PTA; patients developing complications during or after PTA and patients with poorly controlled hypertension or other unstable conditions should not be considered for short-term observation.

The decision for short-term vs. longer-term post-procedural observation must be individualized. A given patient's care may vary from the above recommendation for sound clinical reasons. In each case, the decision must be made by the operating physician after review of all pertinent data.

## **7. QUALITY IMPROVEMENT**

All PTA procedures should be monitored within the overall quality improvement program of the facility. The incidence of complications should be recorded and periodically reviewed for the opportunity to improve care. These data should be collected in a manner which complies with statutory and regulatory peer-review procedures in order to protect the confidentiality of the peer-review data.

## **8. REFERENCES**

1. Standards of Practice Committee of the Society of Cardiovascular and Interventional Radiology. Guidelines for percutaneous transluminal angioplasty. *Radiology* 1990; 177:619-630/*JVIR* 1990; 1:5-15.

2. Standards of Practice Committee of the Society of Cardiovascular and Interventional Radiology.

3. Standards for Interventional Radiology, *JVIR* 1991; 2:59-65.

4. Standards of Practice Committee of the Society of Cardiovascular and Interventional Radiology. Angioplasty Standards of Practice. *JVIR* 1992; 3: 269-271.