CAR Standards for Intravascular Stents

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I. INTRODUCTION AND DEFINITION

Intravascular stents are devices made of metallic coils or mesh that are introduced into the body through a delivery catheter in a collapsed form with a constrained diameter. After the stent is placed at the desired location under fluoroscopic control, it is expanded to a larger diameter by a variety of mechanisms to provide mechanical support to the vessel wall.

As of March 1995, only the Palmaz stent is approved in Canada for intravascular use. However, there are other types of stents which are currently undergoing clinical trials and may only be used on compassionate grounds.

Palmaz stent is a balloon-expandable stent, i.e. it is expanded by inflating the balloon upon which the stent is loaded. It was first introduced to clinical practice in 1987, and there is now a collective experience of over 1,000 stent placements. However, more experience and a longer follow-up period are necessary to establish firm indications for use of this device as compared to balloon angioplasty.

The main function of an intravascular stent is to overcome the flow limiting effect of elastic recoil and intimal dissection induced by balloon angioplasty. The main drawback is the thrombogenicity of the metallic alloy that may necessitate longterm anticoagulation. There is also associated risk of myointimal hyperplasia which results in restenosis.

II. QUALIFICATIONS

As per qualifications for transluminal angioplasty.

III. INDICATIONS AND CONTRAINDICATIONS

A. Indications

Currently iliac artery stenting is indicated in patients with the following conditions:

1. PTA-induced common or external iliac artery dissection

2. Stenoses or occlusions of common or external iliac arteries with inadequate or suboptimal results following balloon angioplasty

3. Recurrent or restenosed lesions

Published series have reported an angiographic patency rate of 92% and a sustained clinical benefit of 68.6% at 43 months follow-up for iliac stenting.

B. Contraindications

1. For iliac artery stenting:

Patients with the following conditions are not suitable candidates for the implantation of the Palmaz stent:

a. Total occlusion of both iliac arteries
b. Aneurysmal dilatation proximal or distal to the occluded site
c. Heavily calcified lesions
d. Post-PTA vessel perforation
e. Marked tortuosity of the iliac arteries which may prevent passage of the stent
f. Stenosis involving the common femoral artery
g. Uncontrollable hypercoagulopathy or bleeding diathesis
h. Complex or ulcerated lesions where there is a strong concern of distal embolization

2. For renal artery stenting:

The use of intravascular stents in the non-ostial portion of the renal artery must be judicious because of the risk of interference with bypass surgery by the stent or associated myointimal hyperplasia. In addition, patients with the following conditions are not suitable candidates for renal artery stenting:

a. Stenoses associated with renal artery aneurysm
b. Heavily calcified lesions
c. Post-PTA vessel perforation
d. Marked tortuosity of the iliac and subclavian arteries which may prevent passage of the stent
e. Uncontrollable hypercoagulopathy or bleeding diathesis

IV. EXAMINATION TECHNIQUES, PERFORMANCE AND RELATED MATTERS

A. Approach and method

The need for a high level of angiographic expertise and high resolution digital subtraction imaging during this procedure for precision in deployment cannot be overemphasized. Currenlty, most investigators are placing the proximal end of the stent flush with the edge of the aortic wall.

B. Complications

Published series have reported a complication rate of 10%. It includes complications associated with any PTA (see the section under PTA) as well as complications specific to intravascular stenting. This latter group consists of technical mishaps which can occur during deployment such as slippage of the stent in relation to the balloon, perforation of the balloon resulting in incomplete expansion of the stent, snagging of the stent on the balloon after deflating the balloon, misplacement of the stent in relation to the target stenosis and distal embolizaton of the stent.

REFERENCES

1. Palmaz IC, Labordo JC, Rivera FJ, et al. Stenting of the iliac arteries with the Palmaz stent: Experience from a multicenter trial. Cardiovasc Intervent Radiol 1992; 15:291-297

2. Becker GJ, Palmaz JC, Rees CR, et al. Angioplasty induced dissections in human iliac arteries: Management with Palmaz balloon expandable stents. Radiology 1990; 176:31-38

3. Rees CR, Palmaz JC, Becker GJ, et al. Palmaz stent in arteriosclerotic stenoses involving the ostia of the renal arteries: Preliminary report of a multicenter study. Radiology 1991; 181:507-514