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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Introduction

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The past decade has seen a dramatic increase in the use of mechanical revascularization techniques to treat coronary artery disease. With ageing of the population, improving angioplasty and surgical techniques, and increasing reliance on more invasive diagnostic strategies, this increased use will continue into the next century, creating even greater pressure on limited health care resources. These concerns have prompted the Council of the Canadian Cardiovascular Society to create this consensus investigation. What are current indications for revascularization? What will direct future revascularization growth? What resources will this growth require?

In answering these questions, the consensus' Primary Panel remained focused on the ultimate goal of revascularization in coronary artery disease treatment strategies: to optimize symptom-free survival at a reasonable cost. All who read this document are a part of the consensus process. We ask that readers adopt this focus so that together we can prepare for the future by agreeing on what constitutes optimal symptom reduction, improved quality-of-life survival and reasonable cost.

0.1 REPORT FORMAT

Chapter 1 describes the revascularization tools at our disposal, with insights into the tool selection process. Each tool has strengths and limitations that must be considered, along with

clinical status, ventricular function and angiographic extent of coronary disease, in selecting a means to improve symptom-free survival. Chapters 2, 3 and 4 address revascularization indications in stable angina, unstable coronary syndromes and perimyocardial infarction syndromes, respectively.

Chapters 5 and 6 examine current revascularization practices. Chapter 5 analyzes trends across Canada, and Chapter 6 places these observations in an international perspective. Regional, national and international catheterization and revascularization rates vary significantly. This cannot be explained by coronary artery disease prevalence statistics but may, in part, be simply different 'styles' of practice due to cultural, economic and political influences. It is clear, however, that the search for a workable definition of procedural appropriateness is universal.

Chapter 7 describes current revascularization resources in Canada with speculations on future resource needs directed by population ageing, expected retirement of current surgeons and interventionalists, and the practice trends speculated upon in clinical Chapters 2, 3 and 4. If the next decade does not see a significant and unexpected reduction in the prevalence of coronary artery disease, the way in which we treat coronary artery disease must be dramatically modified. If it is not, the ageing of our population will soon thrust us into a period of accelerating resource demands for which we are not prepared. Our ability to define the appropriateness of our interventions will be challenged as never before and society will be called upon to redefine its priorities in a continuing state of limited resources. It is then appropriate that we consider the ethical and economic dilemmas that this increase will create. This important process is started in Chapter 8.

The concluding Chapter 9 provides a short term approach to the inevitable result of a clash between limited resources and growing demands, the 'waiting list'. A national observational database to monitor cardiac catheterization and revascularization practices is believed to be key in defining a fair system of rationing resources. This process must begin soon: we are already faced with unacceptable waiting times in many regions and further growth in demand is expected.

In context throughout the document, specific recommendations are highlighted with specification of the grade of the recommendation along with the level of evidence on which the recommendations are based. New to this consensus conference is the use of the new recommendation descriptor 'consensus'. The issues within our terms of reference were broad and recommendations emerged that could not be related easily to literary references. These consensus recommendations represent the majority opinion of the panel members based upon their experience and wisdom. The importance of evidence-based recommendations is acknowledged, however, and the 'consensus' label is used cautiously.

0.2 FROM CONCEPT TO CONSENSUS

Although not within our terms of reference, the Primary Panel feels strongly that recommendations concerning revascularization cannot be made without mention of the importance of secondary prevention. Revascularization is inevitably a palliative approach, often providing only temporary relief of the mechanical problem faced by the coronary circulation. Measures to provide revascularization in coronary artery disease would be incomplete if they did not include a meaningful program of secondary prevention. Cholesterol-lowering therapy has been associated with a decreased risk of ischemic coronary events and with regression of atherosclerosis. However, regression of atherosclerosis has been slight compared with the impact on clinical outcomes (1,2). It has been shown recently that aggressive cholesterol-lowering therapy can reverse endothelial dysfunction in coronary atherosclerosis (2,3).

The Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedure of the American College of Cardiology and the American Heart Association (4,5) is acknowledged. The American College of Cardiology/American Heart Association Task Force committee reports on coronary artery bypass grafting and percutaneous transluminal coronary angioplasty published in 1991 and 1993, respectively, continue to be important reference documents on this subject, and the Primary Panel members carefully considered these documents in drafting this report.

The process of consensus must be responsive to ongoing advances in technology, improved medical treatment options, advances in secondary prevention, and changing societal definitions of what constitutes optimal symptom-free survival and reasonable cost. Presentation of this document is one more step in the process.

Although the consensus results were presented to the Annual Meeting of the Canadian Cardiovascular Society in fall 1995, many suggestions for revision were received after that time. We have attempted to accommodate these suggestions and have actually included references that were published after initial presentation to ensure that the recommendations are still timely given the delay in publication. We believe that the document recommendations and conclusions are relevant to revascularization practice in 1997.

Finally, we acknowledge the cooperation and assistance of the staff of the 63 cardiac catheterization laboratories and 35 surgical units across Canada that administer to the cardiovascular needs of over 28 million Canadians. They promptly responded to our requests for information and insights. To meet the revascularization resource challenges of the future, their collaboration in the process of procedure and waiting list monitoring will be essential.

0.3 RECOMMENDATIONS

Introduction 1. All centres with active revascularization programs should actively support complementary programs of secondary prevention, rehabilitation and lifestyle modification for all patients identified with coronary artery disease.

Grade: A
Level: I

REFERENCES

1. Watts GF, Lewis B, Brunt JNH, et al. Effects on coronary artery disease of lipid-lowering diet, or diet plus clolestyramine, in the St Thomas' Atherosclerosis Regression Study (STARS). Lancet 1992;339:563-9.

2. Anderson TJ, Meredith IT, Yeung AC, Frei B, Selwyn AP, Ganz P. The effect of cholesterol-lowering and antioxidant therapy on endothelium-dependent coronary vasomotion. N Engl J Med 1995;332:488-93.

3. Treasure CB, Klein JL, Weintraum WS, et al. Beneficial effects of cholesterol-lowering therapy on the coronary endothelium in patients with coronary artery disease. N Engl J Med 1995;332:481-7.

4. Ryan TJ, Bauman WB, Kennedy JW, et al. Guidelines for percutaneous transluminal coronary angioplasty. A report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Percutaneous Transluminal Coronary Angioplasty). J Am Coll Cardiol 1993;22:2033-54.

5. Pepine CJ, Allen HD, Bashore TM, et al. ACC/AHA guidelines for cardiac catheterization and cardiac catheterization laboratories. American College of Cardiology/American Heart Association Ad Hoc Task Force on Cardiac Catheterization. J Am Coll Cardiol 1991;18:1149-82.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 1: Revascularization options

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Coronary artery disease (CAD) is the single leading cause of death in Canada. Coronary artery bypass grafting (CABG) and percutaneous transluminal coronary angioplasty (PTCA), the most frequently used techniques for myocardial revascularization, are cornerstones of treatment for patients with CAD. Many factors enter into the procedure selection process. In many cases, the appropriate treatment is not an 'either/or' situation, but an evolution of treatment combining medical management with angioplasty and surgery at different points in time during a patient's disease. This chapter outlines these two very different types of coronary intervention and highlights the merits of and differences between the two procedures as adjuncts to medical therapy. We also discuss the logistic and economic considerations that may influence therapeutic choices.

1.1 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

For discussion purposes, PTCA means balloon angioplasty, directional and rotational atherectomy, laser angioplasty and stenting. PTCA is an easily performed procedure requiring only local anesthesia in awake patients. Patients are generally admitted to hospital the day before or the morning of their procedure and may in uncomplicated cases be discharged within 24 h of their procedure, depending on the primary results. The procedure lasts from 20 mins to several hours, depending on the complexity of the anatomy and the initial arterial response. In some patients, a single inflation can result in an excellent angiographic result; in others, multiple balloon inflations at multiple sites are required. Perfusion balloon angioplasty,

coronary stenting or other interventions may be required to achieve a final satisfactory result. Angioplasty can be performed at any time of the day and at very short notice, but frequently requires surgical backup to deal with the possibility of acute closure or dissection not responding to conventional measures in the catheterization laboratory. A minority of PTCAs require fairly close surgical backup such that, in the event of acute coronary occlusion associated with balloon dilation, emergency surgical revascularization is possible. Emergency surgery for failed PTCA is required in about 2% of cases, but the need has diminished in the stent era (1) and has been further reduced with the availability of glycoprotein (GP) IIb/IIIa receptor antagonists given before and during the angioplasty procedure (2,3). The extent of coordination for surgical backup for a PTCA varies considerably among centres, but it is generally recommended that PTCA be performed only at institutions where onsite surgical backup is available.

1.1.1 Lesion limitations

PTCA has evolved considerably from the initial simple lesions approached by basic equipment to the use of increasingly sophisticated equipment. This evolution has resulted in fewer complications, decreased use of emergency bypass surgery and significantly better symptom outcome (4). There are relatively few anatomical substrates that cannot be approached by PTCA or adjunctive devices. Overall success rates are in the range of 95%, with complications of myocardial infarction (MI) in approximately 3% and need for CABG acutely in fewer than 2% (1,5). More complex lesions must be assessed for the following considerations:

1. likelihood of primary success;
2. likelihood of acute closure;
3. potential for major infarction or cardiovascular collapse in the event of acute closure; and

4. potential for restenosis.

   Specific lesion characteristics are associated with an increased likelihood of primary failure, acute closure and re-stenosis.

5. Chronic total occlusions (6-8). Features include the following:
   a. reduced primary success (50% to 80%);

   b. high risk of early recoil and closure;

   c. low risk of myocardial injury associated with reclosure; and

   d. increased risk of restenosis.

   Other devices and techniques such as laser, stents and rotational atherectomy have been evaluated in this anatomical subset (7,9). The use of coronary stents for total occlusion is an area of interest and is soon to be assessed more rigorously in larger scale randomized trials.

   When a patient was asymptomatic with a total arterial occlusion before becoming symptomatic with disease progression, it is frequently possible to disregard the total occlusion and render the patient asymptomatic again with selective 'culprit-lesion' angioplasty (10). Where a more complete revascularization strategy is thought to be merited (11-13), surgery usually is preferred, although there is preliminary encouragement that the adjunctive use of stenting is associated with substantial restenosis reductions compared with balloon intervention without stenting.

6. Sequential and long lesions (14,15). Features include the following:
   a. reduced primary success (80% to 90%) that has been improved with use of long balloons;

   b. greater risk of acute closure; and

c. increased risk of restenosis.

These lesions are being treated with long balloons, rotational atherectomy and, in some cases, multiple stents. The impact of these strategies on outcome is unclear because no randomized studies specifically dealing with this anatomical subset have been published.

7. Eccentric lesions (14,16,17). Features include the following:
    a. reduced primary success;
    b. high risk of early recoil and acute closure; and
    c. increased restenosis rate.

    The primary success rate has been improved by use of directional coronary atherectomy (DCA) and by primary stenting, with lower risk of acute closure and recoil.

8. Lesions in bends (17,18). Features include the following:
    a. reduced primary success; and
    b. heightened risk of early recoil and acute closure.

    These lesions continue to be a problem for conventional balloon angioplasty. Improvements have been achieved by debulking lesions with rotational atherectomy, but in many cases this device is contraindicated on sharp bends due to the risk of perforation. DCA is not useful in this setting due to the inflexibility of the device, and excimer laser is associated with an increased incidence of vessel perforation. Many of these lesions can be approached with shorter lengths of the rigid Johnson and Johnson stent. Several of the newer stent designs currently being evaluated may prove useful.

9. Calcified lesions (17,19,20). Features include the following:
    a. reduced primary success due to inability to expand the lesion; and
    b. heightened risk of acute recoil and closure.

These lesions continue to pose difficulty for percutaneous techniques, particularly in the elderly population. Rotational atherectomy has improved the primary success rate in calcified lesions (21,22). This device has reduced complication rates in this subset; the laser has failed to do so to the same degree. Increased procedural cost and higher restenosis rates may offset improved primary success with rotational atherectomy in this subset.

10. Ostial lesions. Features include the following:
    a. reduced primary success due to elastic recoil;
    b. increased rate of late recoil;
    c. difficulty with stabilization in the event of acute closure; and
    d. heightened restenosis rates.

    Rotational and directional atherectomy and stents have been tried in this challenging subset, but outcomes are not as good as initially hoped (23,24). Non-Q wave MI is more frequent when this lesion is treated with DCA, stent deployment at ostial locations is more difficult, and, even with stent deployment, elastic recoil is more difficult to prevent.

11. Vein graft lesions (25-27). Features include the following:
    a. reduced primary success due to recoil and higher incidence of dissection;
    b. heightened risk of delayed recoil, graft thrombosis and distal embolism; and
    c. heightened restenosis rates.

    These lesions are particularly amenable to stents, given the larger calibre of vein grafts and the relative ease of stent deployment in grafts. Elective stenting of vein grafts provides a better primary result, less chance of recoil and dissection, and promises to reduce restenosis rates (24,28,29). This is particularly effective with focal disease, but diffusely diseased vein grafts continue to present a major challenge for PTCA. In selected patients who present with an abrupt change in clinical status, the adjunctive

use of thrombolytics and new antiplatelet medications can be of some value. This approach is a particularly attractive alternative to reoperation when there are several patent grafts.

12. Lesions with intimal flaps/spontaneous dissection. Features include the following:
    a. reduced primary success rate; and
    b. greater incidence of recoil and acute closure.

This type of lesion frequently shows minimal response to balloon dilation. DCA to remove the flap or stent deployment to 'tack' it against the wall have been very useful for this type of lesion but have not been rigorously evaluated prospectively.

1.2 CORONARY ARTERY BYPASS GRAFTING

CABG surgery is usually performed through a median sternotomy with institution of cardiopulmonary bypass. To facilitate the surgery, the heart is isolated from the circulation by cross-clamping the aorta. The myocardium is protected during this ischemic period by the intermittent or continuous administration of a cardioplegia solution into the aortic root, directly down the native coronary arteries or patent grafts, or in a retrograde fashion through the coronary sinus. Cardioplegia solutions include high potassium-containing solutions of crystalloid or blood, and the solutions can be administered cold or warm. Mild to moderate systemic hypothermia can be used or alternatively the body can be maintained at normothermia. In specific situations one technique can be superior to another, but, in general, the choice is determined by the experience and training of the surgeons, and all can be associated with good clinical results (30).

Proximal and distal anastomoses are performed with appropriate conduit. The cross clamp is removed, and the heart is reperfused. The patient is then weaned from cardiopulmonary bypass. The procedure requires 3 to 5 h. Hospitalization following uncomplicated CABG is five to seven days. In the early 1970s mortality associated with the CABG procedure was 8% to

15% (31,32). With improved technique, mortality rates decreased to 1% to 2% in the mid-1980s. Now, with increasing age and associated disease, despite improved techniques, mortality is again increasing to 3% to 5% (33). The relatively high procedural risks of the early 1970s should be considered when assessing the implications of randomized trials during that period for today's surgical practice.

1.2.1 Techniques

Internal mammary arteries (IMAs) and saphenous veins are the most commonly used conduits. In most situations a single piece of vein or artery is employed for a single coronary artery bypass. If conduit availability is limited and coronary anatomy is favourable, sequential or skip grafts that use one length of conduit to bypass two or more coronary arteries are possible. Any vessel greater than 1 mm in diameter with a stenosis of 70% or greater is appropriate for grafting (34). The success of the operation is largely dependent on bypassing all appropriate vessels. It can be extremely difficult to predict size of arteries or extent of disease from preoperative angiograms. In some cases the artery is found to be much larger than predicted, while in other situations, arteries may be so diseased that it is impossible to bypass them. Under these circumstances coronary endarterectomy can be performed. This technique involves removal of the inner calcific core and intima of the coronary artery. With appropriate selection of cases, endarterectomy can be performed on the left anterior descending (LAD) artery, the circumflex coronary artery or the right coronary artery, with good clinical results (35-37). *The main indication for this procedure is the presence of diffuse disease at an optimal graft insertion site that could compromise runoff and thereby predispose to early graft closure.*

1.2.1.1 Conduit - venous: The long saphenous vein is the most commonly used conduit for CABG surgery. It provides ample vein for multiple conduits, 15 to 23 cm in length. It is located in the subcutaneous layer along the medial aspect of the leg. Because it has numerous valves, the vein must be used in a reverse fashion. Ten per cent to 15% occlude within three months, or the 'acute period'. Thereafter, there is a 'subacute' period from 30 days to one year in which the occlusion rate is about 5%, followed by a 'chronic' phase with an ongoing 2% per year

occlusion rate, at least for the first five to seven years. After that the attrition rate increases (38). At 10 years, 50% to 60% of the grafts are patent, but 50% of these have angiographic disease (39). Ingestion of acetylsalicylic acid has been advocated as a method of improving early graft patency by minimizing graft thrombosis and perhaps intimal hyperplasia, but this practice is not universal (40,41). *The presence of varicosities or previous vein stripping may limit the availability of this conduit. In addition, the long saphenous vein may have been used in previous CABG or peripheral vascular surgery.*

The short saphenous vein runs in the midportion of the posterior aspect of the calf. It is usually free from varicosities and provides sufficient length for one or two grafts. It is an excellent source of vein if insufficient long saphenous vein is available. Cephalic and basilic veins provide easily harvested long lengths of conduit, but have thin walls and are more friable. The five-year patency rate is only 40% (42,43).

Fresh homologous saphenous veins have been harvested and used. No ABO histocompatibility matching was undertaken and no immunosuppressive agents were administered postoperatively. Repeat angiography up to 44 months postoperatively revealed five of seven grafts to be occluded. Currently, this is not a conduit of choice (44,45).

Cryopreservation of saphenous vein has been attempted intermittently over the past 25 years. Early studies raised concerns regarding long term patency, antigenicity of the vein graft and significant structural changes in the vein graft. The long term results of newer methods of cryopreservation are not yet available. Currently, cryopreserved veins cannot be recommended as an optimal conduit. Glutaraldehyde-fixed umbilical vein has also been used as conduit for CABG. The patency rate was 50% after one year and the vein grafts were predisposed to aneurysmal degeneration. As a consequence, their use has been abandoned (45,46).

1.2.1.2 Conduit - arterial: The IMA is a branch of the subclavian artery running bilaterally along the length of the sternum. It is generally harvested as a pedicle based on the subclavian artery origin and can be used as a single or skip graft. The left IMA is used principally to bypass lesions in the LAD distribution or the circumflex distribution. The right IMA can be used to

bypass the lesions in the LAD, the proximal circumflex or the right coronary artery. The IMA shows no evidence of atherosclerosis in 95% of the population. Patency rates in patients studied by angiography at one and 10 years are 95% and 90%, respectively. Use of the left IMA, particularly to the LAD, has been shown to be associated with increased 10-year survival and decreased incidence of MI (47). Because of the excellent results achieved with use of one IMA, some centres are recommending the routine use of bilateral IMA when a patient is under the age of 60 years. Long term results of this strategy are not yet available, but in appropriate situations bilateral IMA grafting should be considered. Some investigators have suggested that there is an increased rate of sternal wound infection in diabetic patients in whom bilateral mammaries were used. As a consequence, judgement should be used before proceeding with bilateral IMA grafting (48).

Use of the IMA in unstable patients remains controversial. Some surgeons are concerned about the amount of flow in an IMA in an acute situation, the impact of simultaneous use of inotropic agents with arterial grafting and the time required for grafting. There is an important difference in IMA use between acute MI or catheterization laboratory catastrophes and crescendo and 'cooled off' unstable angina. In many unstable angina scenarios most surgeons would not hesitate to use an IMA if indicated. In a retrospective review Cybulsky and Brister (49) reported no increase in morbidity and mortality in selected patients in whom the IMA was used. No prospective studies have been undertaken to clarify this point, however. *It is likely that use of the IMA in unstable situations will be left to the surgeon's judgement for the immediate future.*

The gastroepiploic artery is harvested from the greater curvature of the stomach and, like the IMA, is rarely affected by atherosclerosis. A pedicle graft of 15 cm can be obtained and provides a satisfactory graft to the inferior aspect of the heart. Excellent early and midterm results have been demonstrated (50,51). Currently, grafting with the gastroepiploic artery is recommended in conjunction with bilateral IMA grafting *in young patients* who are candidates for surgery. Long term results of triple arterial grafting are not yet proven (52).

Edwards et al (53) have reported the successful use of the splenic artery as an autogenous pedicled arterial graft. It is approximately 15 cm in length and can be brought through an opening in the diaphragm. They reported a 90% patency rate at one to two years. Concerns were raised regarding long term patency rates because of the presence of atherosclerosis in the artery. In addition, considerable technical difficulties are encountered in harvesting the splenic artery. The artery is quite tortuous with numerous fibrous bands, requiring a meticulous dissection. Usually a concomitant splenectomy is required to avoid a splenic infarction (54,55).

In 1973, Carpentier et al (56) reported their experience employing the radial artery for coronary grafting in 30 patients. Early results were satisfactory with only three grafts showing narrowing. Significant problems were noted with spasm of the artery. In addition, marked intimal hyperplasia was seen within one year (57); the technique was abandoned until recently. Carpentier has again reviewed his experience, which he feels demonstrates good long term patency in the remaining grafts (58). Other investigators have experienced better early success with improved techniques of harvesting grafts, but the long term results are not yet available.

Although there is some midterm satisfaction with the use of the newer arterial conduits as independent grafts, the radial and inferior epigastric arteries also can be attached to the IMA as a Y graft, and the right IMA can be detached proximally and used as a free graft. Together these options can increase the scope of multiple arterial grafting improving long term outlook.

1.2.1.3 Conduit - synthetic: Sauvage et al (59) employed 3.5 mm knitted Dacron filamentous vascular prostheses for an interposition graft between the aorta and the right coronary artery. He subsequently used the conduit for 27 grafts in 16 patients. The patency rate after three months was only 61%. Chard et al (60) subsequently reported the results of polytetrafluoroethylene aortocoronary graft. The patency rates were 64%, 21% and 14% at one, two and four years, respectively. Current synthetic conduits are not recommended for use in conventional CABG (59,60).

1.2.2 Limitations

As with PTCA, there are important lesion and patient-specific factors that present special surgical challenges. Although appropriate preparation for these difficulties can often reduce their negative impact, consideration of these features is important in patient selection deliberations. Some of these situations are listed below.

Diffuse disease distal to optimal points of graft insertion. Adequate runoff is important to both short and long term graft patency (in fact the presence of poor distal runoff is also an indicator of a poor long term angioplasty result).

Re-operations continue to carry an increased perioperative risk due to the prolonged procedure dissection times required, increased risk of late bleeding, reduced supply of conduits and difficulty in securing adequate cardiac protection at induction. This latter concern is particularly important with patent grafts, although newer techniques of retrograde administration of cardioplegia have lowered the risk.

Inadequate available conduits, due to prior graft harvesting, peripheral vascular surgery or peripheral venous insufficiency, adversely influence long term graft patency.

Important comorbidity. Where life expectancy is significantly reduced by concurrent illness, the advisability of an expensive operation is open to question and more aggressive medical measures or palliative angioplasty options should be considered.

Inability to achieve complete revascularization. Careful preoperative assessment of the likelihood of complete revascularization by an operation is crucial. The degree of residual disease after operation along with the degree of left ventricular dysfunction and the patient's age are the most important predictors of an effective long term result (11). This is particularly true when the LAD distribution is not revascularized (13) and when triple vessel disease is present (61). When complete revascularization is not likely and a culprit lesion can be identified, further medical trials or culprit-lesion selective angioplasty may be alternatives (10,12,62).

Atheroembolism. Instrumentation of the ascending aorta is a cause of stroke leading to important morbidity. Screening techniques to identify those at higher risk for this distressing complication are, as yet, unreliable.

Uncertainty associated with multiple artery grafting. The impact of left internal thoracic artery grafting to the LAD on long term outcome has been well documented, but the long term efficacy of multiple arterial grafting has not been subjected to the same rigorous examination. Further, not all surgeons are skilled in the newer techniques of multiple arterial grafting; therefore, regional revascularization decision-making will continue to be influenced by local surgical skills and experience.

1.2.3 Sex-related issues

Cardiovascular disease is the leading cause of death in women as well as men. More women die of heart disease or stroke than of all cancers combined. Women have many of the same risk factors as men (63). Hypertension is nearly twice as common. Diabetes mellitus increases the risk of CAD threefold in women. More women than men have diabetes at the time of their first heart attack. Cholesterol is as significant a risk factor for CAD in women as in men. When the ratio of total cholesterol to high density lipoprotein cholesterol is above 7.5, the likelihood that CAD will develop is equally high in men and women. Before menopause, women have a higher level of the protective high density lipoprotein, but these levels decrease with age, and eventually women are at the same risk as men. Smoking is another strong risk factor for both men and women. The adverse effects are closely related to heart disease and exist both before and after menopause. Women who smoke 25 cigarettes per day have a 25-fold higher rate of MI than women who have never smoked.

Some risk factors are unique to women. Results from early studies on oral contraceptives that contained high doses of estrogen and a progesterone suggested that the likelihood of fatal or nonfatal MI was increased about fourfold. They can also exacerbate other risk factors. It appears that a woman's hormonal status influences her lipid profile in a complex and interrelated fashion. Estrogen raises protective serum high density lipoprotein fraction and

lowers the harmful low density lipoprotein fraction. Progesterone reduces this beneficial effect when combined with estrogens. Triglycerides, which are an independent risk factor in women, are increased with unopposed estrogens, but this harmful effect is cancelled by the addition of progesterone. After menopause, women lose their protective effect of estrogen. Their risk of developing a heart attack dramatically increases. The incidence of CAD in women between the ages of 45 and 50 years is half that of men in the same age group, but by age 55, there is an equal incidence. Estrogen therapy may reduce the incidence of CAD or fatal cardiovascular events by 50%. This reduction in cardiovascular morbidity may outweigh the risks incurred from a slight increase in the incidence of gallstones and endometrial or breast cancer. Finally, there appears to be a positive influence of hormonal replacement on endothelial function and coagulation. At present, women should discuss their decision to use estrogen replacement therapy with a physician (63).

CAD presents differently in men and women. Infarction is more common as the first manifestation of CAD in men than in women. Women present more often with angina. Their symptoms are 'nonclassical', more vague than those generally ascribed to angina. In-hospital mortality following a heart attack is higher for women and following discharge, and more women have recurrent angina, congestive heart failure and reinfarction. Increased age at the time of diagnosis, smaller blood vessel size, a larger infarct size for a similar risk region, higher GP IIb/IIIa receptor concentrations on platelets and more variable vasoreactivity patterns may explain some of these differences, but not all of them (64).

Resting electrocardiograms can show unequivocal evidence of prior infarction or ischemia. There is no difference in exercise test sensitivity or specificity between men and postmenopausal women. When men and women are matched for the presence and severity of CAD, true and false positive results are identical. Thallium-201 scintigraphy increases the sensitivity of exercise stress testing, but sex-related issues can cause difficulty in the interpretation of the images. The accuracy of coronary angiography is not influenced by sex (62).

From a review of the literature, it appears that fewer women are referred for angiography than men (65). Following angiography, appropriate numbers of individuals are referred for PTCA and CABG (66). The decreased incidence of initial referral has been attributed to a perception of poor prognosis with revascularization, physician bias and patient preference. No definitive answer is known. Initial reports in the literature suggested that women face a higher morbidity and mortality with revascularization (67,68). Despite these higher complications, PTCA and CABG are effective methods of revascularization for both men and women in the appropriate setting (69,70).

1.3 INDICATIONS FOR CORONARY REVASCULARIZATION

For coronary revascularization, there are two major classifications of indications. Patients are subjected to revascularization for improvement of survival, or for relief of symptoms as an alternative to medical therapy. Although less common than angina, symptoms that can be relieved by revascularization also include dyspnea resulting from left ventricular dysfunction, pulmonary edema caused by global ischemia and/or severe mitral regurgitation, and symptoms due to ventricular arrhythmias. In the management of silent myocardial ischemia revascularization may be performed either for improvement in survival or as therapy designed to eliminate need for medications and restriction of activity.

Randomized trials undertaken to determine which coronary anatomical subgroups benefit more from surgery than from medical therapy are analyzed in Chapters 2 and 3. There is level I evidence from randomized trials that patients with left main coronary disease, as well as patients with triple vessel coronary disease, moderate symptoms and reduced left ventricular function, benefit from surgery. There are other subsets where surgery is believed to be advantageous, such as with patients with double vessel disease and involvement of the proximal LAD artery, particularly when there is moderate left ventricular dysfunction. For other patients with less extensive disease, CABG offers an excellent mechanism for relief of anginal symptoms with a strong chance of elimination of need for antianginal drug therapy (71,72).

Very few randomized trials of PTCA versus medical therapy have been performed, so there is little evidence with regard to long term prognosis. PTCA is generally not indicated for mortality reduction given that it is not an appropriate procedure for left main coronary disease or triple vessel coronary bypass grafting except in selected circumstances. PTCA is an excellent alternative to medical therapy for relief of symptoms in many patients depending on the specific coronary anatomy and medical syndrome. In multivessel coronary disease, there are clearly patients who are best dealt with by coronary bypass surgery and others more appropriately dealt with by PTCA. There are several randomized trials of CABG versus PTCA for treatment of the patient in the overlap category of double vessel coronary disease: GABI (German Angioplasty Bypass surgery Investigation); CABRI (Coronary Artery versus Bypass Revascularization Investigation); ERACI (Estudio Randomizado Argentino de Angioplastia vs CIrugia); RITA (Randomized Intervention Treatment of Angina); EAST (Emory Angioplasty versus Surgery Trial); and BARI (Bypass Angioplasty Revascularization Investigation) (72-74). The preliminary results of these trials suggest that either procedure is an option with comparable morbidity and mortality, but that CABG offers a 'one-shot' procedure whereas PTCA may require multiple procedures over the shorter term (73-76). These trials were not undertaken in the 'stent era', a fact that may limit their applicability to current day decision-making.

The choice of CABG versus PTCA is a judgement call and requires an evaluation of risks versus benefits for each procedure or situation. Because disease progression tends to favour proximal arterial segments, the distal targeting of surgical revascularization may offer a theoretical advantage over PTCA in the long term. PTCA usually involves dilation of more proximal segments. Later coronary disease progression in the midsegments of vessels may lead to the need for repeat revascularization more often with PTCA than with CABG. In reality, however, most repeat angioplasties are due to either restenosis of a proximal dilated site or disease progression in the proximal portions of other arteries not previously dilated. The two procedures continue to be complementary. When PTCA fails, CABG is an option. On the other hand, PTCA can be performed for patients who have had CABG and have later developed significant disease progression in the native vessels beyond a graft anastomosis, in a vessel previously not bypassed or a significant stenosis in the bypass graft itself.

The growth of PTCA in North America has been rapid and in most centres PTCA is now performed more often than CABG. A review of outcomes of all patients subjected to diagnostic catheterization suggests that 25% eventually undergo CABG or other cardiac surgery and a slightly higher percentage will undergo PTCA (77,78). (See Chapter 5 for current Canadian revascularization patterns.)

1.4 RISK AND OUTCOME

Morbidity and mortality associated with a procedure have four principle components: first, random events over which the physician, surgeon or patient have no control; second, the 'learning curve', which includes human failure in judgment or technique that potentially could be decreased with increased knowledge or expertise; third, severity of associated noncardiac disease; and fourth, severity of cardiac disease (79). With increasing medical knowledge and concentration of experience with high volume and well trained teams, the morbidity and mortality associated with the first two components can be decreased.

The role of associated noncardiac disease in morbidity and mortality has long been recognized. PTCA and CABG differ to a significant degree with regard to concomitant medical problems that contraindicate intervention. For PTCA these are related to technical factors such as lack of availability of access to the vascular system via the brachial, axillary, radial or femoral approach. Medical conditions such as severe renal failure (80), cardiogenic shock and sepsis do not preclude the possibility of performance of this procedure as a life-saving measure, but risks are certainly increased. Terminal disease of any origin is a well accepted contraindication to CABG because of poor long term survival, but PTCA may provide acceptable palliation in certain circumstances. Studies have shown that risks of CABG increase with age, diabetes, hypertension and morbid obesity (81,82). Other diseases such as pulmonary and renal dysfunction certainly are associated with increased risk at surgery but are difficult to quantify. More research is needed to define better the role of PTCA and CABG in complex clinical situations.

The fourth component contributing to the morbidity and mortality of these procedures is the severity of the cardiac disease. These include, among others, left ventricular function, anatomy, and clinical and lesion instability. There are certain subsets of patients with triple vessel coronary disease in whom collateral arterial support to the vessels undergoing dilation makes the risk of PTCA only slightly greater than that of diagnostic cardiac catheterization. Clearly, in some patients CABG is a much lower risk procedure. This applies in situations where the risk of acute closure of the coronary artery undergoing dilation would be associated with such major hemodynamic disturbance that the patient could not be stabilized for transport to the operating room for emergency CABG.

Increasing attention is being placed on reduction of procedural morbidity and mortality. It is well recognized that the patient with more severe disease has a greater absolute benefit of surgery than the patient with less severe disease. By overly focusing on decreased morbidity and mortality as the standard, we run the risk of denying therapy to those who may benefit most.

1.5 AGE CONSIDERATION

Age continues to be an important consideration for both PTCA and CABG. In elderly patients, PTCA is associated with a slightly reduced primary success rate due to the presence of more heavily calcified coronary arteries and the failure to achieve a good response to intervention. Elderly patients have more tortuous vessels, which may affect guide catheter advancement or manipulation. The presence of concomitant problems such as renal failure may increase the complication rates associated with the procedure to a minor degree (83-85).

The mean age of patients undergoing CABG has increased significantly in the past decade. This is certain to continue when anticipated trends in population ageing take place (see Chapter 7). With increasing age, there is an increase in the extent of vessel disease and a decrease in left ventricular function. Contributing to this trend of increasing disease severity is the mortality reduction realized through thrombolytic therapy. As underlying disease in the surviving patients continues to progress they will eventually return for assessment with more complex and advanced disease. Studies have shown that CABG can be performed with an

increased but acceptable mortality despite increasing age. It is, however, associated with prolonged hospital stay and increased morbidity, and thus an increase in resource allocation (86,87).

Given the coronary disease complexity and the reduced revascularization longevity benefit that may come with advancing age, should age be a factor in determining waiting list priorities or even in determining whether a patient is a suitable candidate for revascularization? On ethical grounds, this consensus has concluded that age alone should not be a factor (see Chapter 8). Age, however, should enter into the angioplasty or surgery revascularization decision-making process along with the many other factors known to influence the risk-benefit balance. If arbitrary age limits are to be pursued for revascularization, this should be approached on a societal level. Delegating to clinicians the responsibility for imposing these age limits may conflict with their patient advocacy role.

1.6 CURRENT AND FUTURE DEVELOPMENTS

Because the benefits of surgery seemed to improve with time after the randomized trials of the 1970s (88), it is unlikely that advances in medical therapy will reduce the need for revascularization. To the contrary, the need will likely rise with the average age of the population and improved survival following thrombolytic therapy and direct angioplasty for acute infarction. Similarly, despite the persisting problem of restenosis, acute and chronic angioplasty results have improved (4), and this trend is expected to continue, particularly due to encouraging results with stenting.

1.6.1 Percutaneous transluminal coronary angioplasty

There are a number of PTCA alternatives to balloon dilation. Those currently approved are laser, rotational atherectomy, directional atherectomy and stents.

Laser angioplasty has undergone considerable evaluation and has not been shown to provide significant improvement in either primary or long term success except in selected series of

complex lesions (89). Additionally, the considerable increase in expense makes this procedure relatively unattractive for consideration in the health care system where resources are limited.

DCA offers the advantage of a better primary result in some patients with complex coronary anatomy, but is generally restricted to more proximal vessels. The primary success rate appears to be marginally better in some studies, but the periprocedure infarction rate may be increased slightly, and evidence demonstrates that restenosis is not affected by this procedure (90,91). The OARS (Optimal Atherectomy Re- stenosis Study), BOAT (Balloon vs Optimal Atherectomy Trial) and other trials evaluating ultrasound-guided Îoptimal atherectomyâ have shown that better primary results may be achieved, but the impact on restenosis is not yet determined (92,93). To achieve optimal results from DCA, adjunctive balloon dilation was required in almost all cases. Again, the additional expense of this procedure and the lack of a significant impact on restenosis rates have limited its use to particular anatomical subsets.

Rotational coronary atherectomy has the advantage of better primary results in specific anatomical subsets where more diffuse disease and calcified vessels are present (21,22,94). Although this device has improved the success rate in the complex lesions mentioned, periprocedural infarction from debris embolization continues to be a problem. Better primary success is at the cost of considerably greater expense and reported higher restenosis rates, particularly in type C lesions, as shown in the ERBAC (Excimer laser, Rotablator and Balloon Angioplasty Comparison) study (28). In type C lesions, the restenosis rate was greater than 60%. To achieve a high primary success rate with rotational atherectomy, adjunctive balloon dilation is required in the majority of cases. Additionally, multiple burrs are frequently necessary. This increases the cost of the procedure to several times that of balloon angioplasty.

Coronary stenting is a primary procedure that appears to achieve comparable or slightly improved primary success rates by virtue of achievement of greater luminal gain by prevention of elastic recoil (24,25,29,95-101). There appears to be a modest reduction in restenosis rates as determined by randomized studies (99,102), but this has been offset by considerable

increase in expense and inconvenience, particularly related to the more complex anticoagulation process associated with stenting. Recently, coronary ultrasonic observations during stenting have led to the approach of deploying stents with high balloon inflation pressures (1400 to 2000 kPa), which has led to a dramatic reduction in subacute thrombosis rate and eliminated the need for warfarin (103). Patients can now be treated with acetylsalicylic acid and ticlopidine and safely discharged on the day after a successful, uncomplicated procedure. Preliminary data are encouraging. This new approach may lead to important restenosis rate and cost reductions for angioplasty (103).

The interventionalists on the Primary Panel and many secondary reviewers feel that the importance of 1995 stenting practice to the recommendations of this consensus process must be stated strongly, even though published support for this strong sentiment is lagging. Evidence of the efficacy of this technique in improving procedural safety, reducing restenosis rates and facilitating a cost effective approach to many patient subgroups is rapidly accumulating and has had strong support at national and international meetings. The published BENESTENT (BElgian NEtherlands STENT study) and STRESS (STent REstenosis Study), confirming increased safety and reduced restenosis with stenting, together randomized more patients than were included in the widely quoted CASS (Coronary Artery Surgery Study). Improved results of stent delivery and antiplatelet therapy obtained in common practice since these two trials were conducted clearly confirm that this device is the single largest advance in nonsurgical revascularization since the development of the angioplasty balloon. Further, recent surgery versus angioplasty randomized trials were performed without current stenting practices, throwing the credibility of their conclusions concerning the need for recurrent procedures into question.

Complementing the advances made with stent technology is the recent addition of more potent antiplatelet therapies that significantly reduce angioplasty complication, particularly in higher risk angioplasty patients and in those with unstable pain syndromes. Recent evidence suggests that the use of the GP IIb/IIIa receptor blocker, abciximab, significantly reduces mortality, urgent revascularization and particularly non-Q wave infarction during and around

the time of angioplasty (2,3). There are important cost issues involved because the cost of this drug exceeds the cost of most stents, adding to the forces driving a higher angioplasty procedural cost.

There may well be further technical advances for these options in percutaneous transluminal coronary revascularization or development of entirely new approaches in the future. Major advances in laser therapy do not appear to be forthcoming. Work is being done to develop more flexible and lower profile DCA catheter systems, which may allow access to the more distal coronary circulation. There do not appear to be any major advances imminent in rotational atherectomy. Numerous companies are working aggressively with coronary stent designs to allow for stents that can be delivered to more distal coronary segments, through bends, or actually be placed in angled lesions or bends in vessels. Additionally, biodegradable stents and stents with drug-eluting coatings are being developed to reduce stent thrombogenicity and directly inhibit fibrocellular proliferation. The result would be a reduction in abrupt closure and reduced restenosis rates at the site of stent deployment.

1.6.2 Coronary artery bypass grafting

Despite the increasing use of PTCA as a revascularization technique, the frequency of CABG has not declined. It is unlikely that any developments in PTCA will alter this relationship. CABG has maintained a very acceptable surgical risk over time despite increasing complexity of coronary anatomical substrate and performance of surgery on progressively older patients with more concomitant medical problems. As further described in Chapter 7, the average age of CAD patients is expected to rise, increasing the likelihood of 'surgical disease'. This type of patient will probably remain in the surgical arena. The ability to provide surgery safely to much sicker patients relates to significant improvements in surgical techniques and myocardial preservation. The increasing use of arterial conduit has resulted in improved long term patency. Use of other conduits may lead to further improvements in short and long term bypass graft patency. Alternatively, pharmacological advances in antiplatelet or antithrombin therapy may increase the long term patency of grafts (104).

Despite the use of arterial conduits and new pharmacological drugs, cardiac surgeons will be faced with an increased number of second, third and fourth operations upon an increasingly aged and medically compromised population. Risks of reoperation are increased over those of primary procedures because of the more diffuse nature of the coronary disease, increased technical difficulty, the difficulties of myocardial protection, the limitation of conduit and increased comorbidity. New strategies will have to be developed to deal with these increasingly frequent problems (105).

1.7 AVAILABILITY OF PROCEDURES

1.7.1 Resources

Both PTCA and CABG require the availability of a complex support system and in Canada are generally limited to tertiary care centres, often with university affiliations. Given the finances involved in establishing such programs, there is a general restriction in the availability of these services according to strict criteria for patient need. Provincial ministries of health regulate this. The service supply:demand ratio varies somewhat from province to province across the country. The waiting list for these procedures is the function of a number of variables. For PTCA, it is primarily related to the number of procedures that can be performed on any given day. Depending on the institution, the wait can be a function of the capacity of the cardiac catheterization laboratory, reduced availability of hospital beds to recuperate patients or the ongoing requirement in a few institutions for coordination of surgical backup. If surgical backup were continually available and there were no limits in availability of hospital beds, as many as six to eight angioplasties could be performed per day in each catheterization procedure room. In general, the above factors govern the number of PTCAs, but in most institutions there is a further restriction on the number of procedures per day depending on availability of finances dictated by the provincial ministry of health. PTCA has the additional advantage of requiring a lower intensity of surveillance of the patient following the procedure than with CABG.

CABG requires a more complex logistical arrangement. Patients are generally admitted one to two days before surgery and remain in the intensive care unit for 12 to 48 h following the procedure. Some centres are moving to same-day admissions for surgery in an effort to

decrease costs. The patient then convalesces on a surgical ward for an additional four to 10 days, depending on the presence of complications, general health and the age of the patient. Factors limiting the performance of cardiovascular surgery are availability of operating rooms with the extensive support staff, availability of surgical intensive care unit beds and availability of general ward beds for patient convalescence. On average, two to three surgical procedures can be performed per operating room theatre per day. Thus, CABG is associated with considerable resource consumption. In a health care system with limited resources, funding available within the system influences waiting time for surgery. With a shortfall of funding, waiting time for surgery increases. In general, urgent or emergent surgery is done first, thus increasing elective waiting time.

(See Chapters 5, 6, 8 and 9 for more discussion on waiting list issues.)

1.7.2 Costs

PTCA and CABG are high technology procedures. Clearly, for either procedure there is considerable expenditure of health care resources. For CABG, these resources are predominately used for a Îone-shotâ procedure. For PTCA, there must be consideration of the possible need for multiple procedures when considering the relatively high incidence of coronary restenosis. With increasing frequency, PTCA and CABG are used as complementary procedures. In young patients PTCA may be used initially to delay surgery for as long as possible. PTCA is an excellent alternative in some situations of graft stenosis, enabling a patient to avoid reoperation. These two methods of coronary revascularization consume a significant proportion of health care resources, and future accessibility to these services will clearly depend on the budgets determined by hospital administrators and provincial ministries of health. The cost issues need to be carefully assessed and monitored. They include consideration of the cost of medication to patients or insurance carriers, actual procedural costs and costs of unemployment insurance, third-party insurance carriers and welfare while patients are unable to work.

In performing a cost-benefit analysis one must consider the cost to the health care systems in providing PTCA or CABG to the patient. Second, in terms of benefit, one can look at the

improvement in quality of life and reduction or elimination of expenses that might have otherwise occurred if revascularization had not been performed. Over the long term after intervention, there is potential reduction in payments of disability by private insurers and/or the federal social service system, and in the need for expensive medication and costs associated with recurrent admissions to hospital. The question of which procedure is more cost effective depends very much on the clinical and anatomical subsets approached, and is being analyzed in conjunction with randomized trials comparing those two procedures.

To overcome the financial constraints of the Canadian system on the practice of PTCA, some institutions have adopted the practice of reuse of balloon catheters that, according to manufacturersâ instructions, are intended for single use only. The safety of this approach is still controversial (106).

Also gaining momentum in Canada is the practice of *single-stage revascularization or ad hoc angioplasty,* where interventional procedures are performed at the time of the diagnostic catheterization. The practice still varies widely, with use of this approach in 5% to 60% of angioplasty volume being reported (personal communication). The approach is particularly suited to acute MI (107) and when restenosis is suspected on clinical grounds, but it is frequently employed in unstable angina scenarios as well, where the culprit lesion is obvious and there is a compelling clinical need to intervene (10,61). From a resource perspective, the practice has distinct advantages, although there is a concern that adequate deliberation, 'sober second thought' and appropriate patient discussion may be absent unless the process is carefully regulated. This practice also creates a problem for registries monitoring angiographic and interventional rates (77,78). It is recommended that combined procedures be designated as such.

1.8 CONCLUSION

PTCA and CABG are effective methods of revascularization in CAD. In appropriate circumstances, they provide good relief of angina and they may provide survival benefit. With evolving technologies, their relationship to one another will constantly change. The principal

hurdle facing cardiologists and cardiac surgeons in the next decade will be the provision of services under a situation of limited resources.

1.9 RECOMMENDATIONS

1.9.1 Angioplasty and surgery are highly dependent on the skill and experience of individual operators. This 'local factor' should be considered along with literature recommendations when dealing with individual patients.

Grade: Consensus

1.9.2 Selection of a revascularization technique is strongly influenced by mortality reduction expectations in multivessel disease. However, the final choice of technique should be made only after close consultation with surgeons and interventional cardiologists.

Grade: Consensus

1.9.3 The IMA should be used during bypass surgery in most patients regardless of age. This is particularly true for the LAD system.

Grade: C

Levels: III, IV and V

1.9.4 Although the need for surgical backup of angioplasty is uncommon, onsite or rapidly available surgical backup continues to be prudent.

Grade: Consensus

1.9.5 The consensus reaffirms the unique diagnostic and therapeutic problems associated with coronary artery disease in women. These issues warrant further study by the Canadian Cardiovascular Society.

Grade: Consensus

REFERENCES

1. Haraphongse M, Na-Ayudhya RK, Burton J, et al. Clinical efficacy of emergency bypass surgery for failed coronary angioplasty. Can J Cardiol 1990;6:186-90.

2. Randomised placebo-controlled trial of abciximab before and during coronary intervention in refractory unstable angina: the CAPTURE Study. Lancet 1997;349:1429-35.

3. Platelet glycoprotein IIb/IIIa receptor blockade and low-dose heparin during percutaneous coronary revascularization. The EPILOG Investigators. N Engl J Med 1997;336:1689-96.

4. Seydoux C, Goy JJ, Beuret P, et al. Effectiveness of percutaneous transluminal coronary angioplasty in cardiogenic shock during acute myocardial infarction. Am J Cardiol 1992;69:968-70.

5. Landa C, Lange RA, Hillis LD. Medical progress: percutaneous transluminal coronary angioplasty. N Engl J Med 1994;330:981-93.

6. Stone GW, Rutherford BD, McConahay DR, et al. Procedural outcome of angioplasty for total coronary artery occlusion: an analysis of 971 lesions in 905 patients. J Am Coll Cardiol 1990;15:849-56.

7. Medina A, Melian F, Suarez de Lezo J, et al. Effectiveness of coronary stenting for the treatment of chronic total occlusion in angina pectoris. Am J Cardiol 1994;73:1222-4.

8. Kahn JK, Rutherford BD, McConahay DR, et al. Initial and long-term outcome of 83 patients after balloon angioplasty of totally occluded bypass grafts. J Am Coll Cardiol 1994;23:1038-42.

9. Danchin N, Cassagnes J, Juillier Y. Balloon angioplasty versus rotational angioplasty in chronic coronary occlusions (The Barocco Study). Am J Cardiol 1995;85:330-4.

10. Wohlgelernter D, Cleman M, Highman HA, Zaret BL. Percutaneous transluminal coronary angioplasty of the 'culprit lesion' for management of unstable angina pectoris in patients with multivessel coronary artery disease. Am J Cardiol 1986;58:460-4.

11. Jones EL, Craver JM, Guyton RA, Bone DK, Hatcher CR Jr. Importance of complete revascularization in performance of the coronary bypass operation. Am J Cardiol 1983;51:7-12.

12. Breisblatt WM, Barnes JV, Weiland F, Spaccavento LJ. Incomplete revascularization in multivessel percutaneous transluminal coronary angioplasty: the role for stress thallium-201 imaging. J Am Coll Cardiol 1988;11:1183-90.

13. Lawrie GM, Morris GC Jr, Silvers A, et al. The influence of residual disease after coronary bypass on the 5-year survival rate of 1274 men with coronary artery disease. Circulation 1982;66:717-23.

14. Meier B, Gruentzig AR, Hollman J, et al. Does length or eccentricity of coronary stenoses influence the outcome of transluminal dilatation? Circulation 1983;67:497-9.

15. Ischinger T, Gruentzig AR, Meier B, Galan K. Coronary dissection and total occlusion associated with percutaneous transluminal coronary angioplasty: significance of initial angiographic morphology of coronary stenoses. Circulation 1986;74:1371-8.

16. Hirshfeld JW, Schwartz JS, Jugo R, et al. Restenosis after coronary angioplasty: a multivariate statistical mode to relate lesion and procedure variables to restenosis. J Am Coll Cardiol 1991;18:647-56.

17. Savage MG, Goldberg S, Hirshfeld JW, et al. Clinical and angiographic determinants of primary coronary angioplasty success. M-HEART Investigators. J Am Coll Cardiol 1991;17:22-8.

18. Ellis SG, Roubin GS, King SB III. Importance of stenosis morphology in the estimation of restenosis risk after elective percutaneous transluminal coronary angioplasty. Am J Cardiol 1989;63:30-4.

19. Mintz GS, Douek P, Pichard AD, et al. Target lesion calcification in coronary artery disease; an intravascular ultrasound study. J Am Coll Cardiol 1992;20:1149-56.

20. Raizner AE, Hust RG, Lewis JM, et al. Transluminal coronary angioplasty in the elderly. Am J Cardiol 1986;57:29-32.

21. Stertzer SH, Rosenblum J, Shaw RE, et al. Coronary rotational ablation: initial experience in 302 procedures. J Am Coll Cardiol 1993;21:287-96.

22. MacIsaac AI, Whitlow PL, Cowley MJ, Buchbinder M. Coronary rotational atherectomy for calcified and non calcified lesions. Final registry analysis. J Am Coll Cardiol 1994;(Suppl):285A. (Abst)

23. Boehrer JD, Ellis SG, Pieper K. Directional atherectomy versus balloon angioplasty for coronary ostial and non-ostial left anterior descending coronary artery lesions: results from a randomized multicenter trial. J Am Coll Cardiol 1995;25:1380-6.

24. Richavia E LF, Macho G. Stent implantation of saphenous vein graft aorto-ostial lesions in patients with unstable ischemic syndromes: immediate angiographic results and long-term clinical outcome. J Am Coll Cardiol 1995;25:866-70.

25. Rocha-Singh K, Morris N, Wong SC, Schatz RA, Teirstein PS. Coronary stenting for treatment of ostial stenosis of native coronary arteries or aortocoronary saphenous venous grafts. Am J Cardiol 1995;75:26-9.

26. Holmes DR Jr, Topol EJ, Califf RM. A multicentre randomized trial of coronary angioplasty versus directional atherectomy for patients with saphenous vein bypass graft lesion. Circulation 1995;91:1966-74.

27. Fenton SH, Fischman DL, Savage MP, et al. Long-term angiographic and clinical outcome after implantation of balloon-expandable stents in aortocoronary saphenous vein grafts. Am J Cardiol 1994;74:1187-91.

28. Piana RN, Moscucci M, Cohen DJ. Palmaz-Schatz stenting for treatment of focal vein graft stenoses: immediate results and long-term outcome. J Am Coll Cardiol 1994;23:1296-304.

29. Savage M, Douglas J, Fischman D, et al. Coronary stents versus balloon angioplasty for aorto-coronary saphenous vein bypass graft disease: interim results of a randomized trial. J Am Coll Cardiol 1995;(Suppl):79A. (Abst)

30. Kirklin JW, Barratt-Boyes BG. Myocardial management during cardiac surgery with cardiopulmonary bypass in cardiac surgery. In: Kirklin JW, Barratt-Boyes BG, eds. Cardiac Surgery: Morphology, Diagnostic Criteria, Natural History, Techniques, Results, and Indications, 2nd edn. New York: Churchill Livingstone, 1993:129-65.

31. Effler DB, Favaloro RG, Groves LK, et al. The simple approach to direct coronary artery surgery. J Thorac Cardiovasc Surg 1971;62:503-10.

32. Johnson WO, Lepley D. An aggressive surgical approach to coronary disease. J Thorac Cardiovasc Surg 1970;59:128-38.

33. Jones EL, Weintraub WS, Craver JR, Guyton RA, Cohen CL. Coronary bypass surgery. Is the operation different today? J Thorac Cardiovasc Surg 1991;101:108-15.

34. Green GE, Stertzer SH, Reppert EH. Coronary arterial bypass grafts. Ann Thorac Surg 1968;5:443-50.

35. Livesay JJ, Cooley DA, Hallman GL, et al. Early and late results of coronary endarterectomy: analysis of 3,369 patients. J Thorac Cardiovasc Surg 1986;92:649.

36. Ladowski JS, Schatzlein MH, Underhill DJ, Peterson AC. Endarterectomy, vein patch and mammary bypass of the anterior descending artery. Ann Thorac Surg 1991;52:1187-9.

37. Goldman BS, Christakis GT. Endarterectomy of the left anterior descending coronary artery. J Card Surg 1994;9:89-96.

38. Pilote L, Califf RM, Sapp S, et al. Regional variation across the United States in the management of acute myocardial infarction. N Engl J Med 1995;333:565-72.

39. Cybulsky I. An inside look at coronary bypass grafting. Cardiology 1994;May:53-60.

40. Chesebro JH, Fuster V, Elvebach LK, et al. Effect of dipyridamole and aspirin on late vein graft patency after mammary bypass operation. N Engl J Med 1984;310:209.

41. Goldman S, Copeland J, Maritz T, et al. Saphenous vein graft patency one year after coronary artery bypass surgery and effects of antiplatelet therapy. Circulation 1989;80:1190-7.

42. Stoney WS, Alford WC, Burrus GR, Glassford DM Jr, Petracek MR, Thomas SF Jr. The fate of arm veins for aorto-coronary bypass grafts. J Thorac Cardiovasc Surg 1984;88:522-7.

43. Wignberg DS, Boeve WJ, Ebels T, et al. Patency of arm vein grafts used in aortocoronary artery bypass surgery. Eur J Cardiothorac Surg 1990;4:510.

44. Bical O, Bachet J, Laurian C, et al. Aortocoronary bypass with homologous saphenous vein. Long term results. Ann Thorac Surg 1980;30:550-7.

45. Tice PA, Zubino VR, Isem OW, Cunningham N, Engleman RM. Coronary artery bypass with freeze-preserved saphenous vein allografts. J Thorac Cardiovasc Surg 1976;71:378-82.

46. Silver GM, Ratski GE, Stutzman FL, Wood NE. Umbilical vein for aortocoronary bypass. Angiology 1982;33:450-3.

47. Loop FD, Lytle BW, Cosgrove DM, et al. Influence of the internal mammary artery graft on 10 year survival and other cardiac events. N Engl J Med 1986;314:1.

48. Galbut DL, Traad EA, Dorman MJ, et al. Seventeen-year experience with bilateral internal mammary artery grafts. Ann Thorac Surg 1990;49:195-201.

49. Cybulsky IJ, Brister SJ. The influence of IMA use on mortality in patients undergoing CABG. Can J Cardiol 1993;9:122E. (Abst)

50. Pym J, Brown PM, Charette EJP, Parker JO, West RO. Gastroepiploic-coronary anastomosis. A viable alternative bypass graft. J Thorac Cardiovasc Surg 1987;94:256-9.

51. Suma H, Wanibuchi Y, Terada Y, et al. The right gastroepiploic artery graft. Clinical and angiographic midterm results in 200 patients. J Thorac Cardiovasc Surg 1993;105:615.

52. Barner HB, Vardhan RJ. Complete myocardial revasculoarization with arterial conduit. In: Karp RB, Laks H, Wechsler A. Advances in Cardiac Surgery. St Louis: Mosby Year Book, 1994:27-45.

53. Edwards WS, Lewis CE, Blakely WR, et al. Coronary artery bypass with internal mammary and splenic artery grafts. Ann Thorac Surg 1973;15:35-40.

54. Larsen A, Johansen A, Andersen D. Gastric arteriosclerosis in elderly people. Scand J Gastroenterol 1969;4:387-9.

55. Mueller CF, Lewis CE, Edwards WS. The angiographic appearance of splenic to coronary artery anastomosis. Radiology 1973;106:513-6.

56. Carpentier A, Guermonprez JL, Deloch A, et al. The aorta to coronary radial artery bypass graft. Ann Thorac Surg 1973;16:111-8.

57. Curtiss JJ, Stoney WS, Alford WC Jr, Burrus GR, Thomas CS Jr. Intimal hyperplasia: a cause of radial artery aorto-coronary bypass graft failure. Ann Thorac Surg 1975;20:628-35.

58. Acar C, Forge A, Chardigny C, et al. Use of the radial artery for coronary artery bypass. A new experience after 20 years. Arch Mal Coeur Vaiss 1993;86:1683-9.

59. Sauvage LR, Schloemeur K, Wood SJ, Logan G. Successful interposition synthetic graft between aorta and right coronary artery. J Thorac Cardiovasc Surg 1976;72:418-42.

60. Chard RB, Johnson DC, Dunn GR, Cartmill TB. Aorto-coronary bypass grafting with polytetrafluoroetylene conduits. J Thorac Cardiovasc Surg 1987;132:134.

61. Bell MR, Gersh BJ, Schaff HV, et al. Effect of completeness of revascularization on long-term outcome of patients with triple vessel disease undergoing coronary artery bypass surgery. A report from the Coronary Artery Surgery Study (CASS) Registry. Circulation 1992;86:446-57.

62. de Feyter PJ, Serruys PW, Arnold A, et al. Coronary angioplasty of the unstable angina related vessel in patients with multivessel disease. Eur Heart J 1986;7:460-7.

63. Peberdy MA, Ornato JP. Coronary artery disease in women. Heart Dis Stroke 1992;1:315-9.

64. Manson JE. Postmenopausal hormone therapy and atherosclerotic disease. Am Heart J 1994;128:1337-43.

65. Ayanian JZ, Epstein AM. Differences in the use of procedures between women and men hospitalized for coronary heart disease. N Engl J Med 1991;325:221-5.

66. Steingart RM, Parker M, Hamm P, et al. Sex differences in the management of coronary artery disease. N Engl J Med 1991;325:226-30.

67. Greenberg MA, Mueller HS. Why the excess mortality in women after PTCA? Circulation 1993;87:1030-2.

68. Arnold AM, Mick MJ, Piedmonte MR, Simpfendorfer C. Gender differences for coronary angioplasty. Am J Cardiol 1994;74:18-21.

69. Cowley MJ, Mullin SM, Kelsey SF, et al. Sex differences in early and long-term results of coronary angioplasty in NHLBI PTCA Registry. Circulation 1985;71:90-7.

70. Eysman SP, Douglas PS. Reperfusion and revascularization strategies for coronary artery disease in women. JAMA 1992;268:1903-7.

71. Yusuf S, Zucker D, Peduzzi P, et al. Effect of coronary artery bypass graft surgery on survival. Overview of ten year results from randomised trials by the Coronary Artery Bypass Graft Surgery Trialists Collaboration. Lancet 1994;344:563-70.

72. Varnauskas E, European Coronary Surgery Study Group. Twelve-year follow-up of survival in the randomized European Coronary Surgery Study. N Engl J Med 1988;319:332-7.

73. Coronary angioplasty versus coronary artery bypass surgery: The Randomized Intervention Treatment of Angina (RITA) trial. Lancet 1993;341:573-80.

74. Eleven-year survival in the Veterans Administration randomized trial of coronary bypass surgery for stable angina: The Veterans Administration Coronary Artery Bypass Surgery Cooperative Study Group. N Engl J Med 1984;311:1333-9.

75. King SB 3rd, Lembo NJ, Weintraub WS, et al. A randomized trial comparing coronary angioplasty with coronary bypass surgery. Emory Angioplasty versus Surgery Trial (EAST) [see comments]. N Engl J Med 1994;331:1044-50.

76. Hamm CW, Reimers J, Ischinger T, Rupprecht HJ, Berger J, Bleifeld W. A randomized study of coronary angioplasty compared with bypass surgery in patients with symptomatic multivessel coronary disease. German Angioplasty Bypass surgery Investigation (GABI) [see comments]. N Engl J Med 1994;331:1037-43.

77. Higginson LAJ, Cairns JA, Smith ER. Rates of cardiac catheterization, coronary angioplasty and coronary artery bypass surgery in Canada (1991). Can J Cardiol 1994;10:728-32.

78. Higginson LAJ, Cairns JA, Keon WJ, Smith ER. Rates of cardiac catheterization, coronary angioplasty and open-heart surgery in adults in Canada. Can Med Assoc J 1992;146:921-5.

79. Jones RH. Comment: in search of the optimal surgical mortality. Circulation 1989;79:I132-6.

80. Reusser LM, Osborn LA, White HJ, Sexon R, Crawford MH. Increased morbidity after coronary angioplasty in patients on chronic hemodialysis. Am J Cardiol 1994;73:965-7.

81. Parsonnet V, Dean D, Bernstein AD. A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart disease. Circulation 1989;79:I3-12.

82. Christakis GT, Ivanov J, Weisel RD, Birnbaum PL, David TE, Salerno TA. The changing pattern of coronary artery bypass grafting. Circulation 1989;80:I151-61.

83. Mick MJ, Simpfendorfer C, Arnold AZ, et al. Early and late results of coronary angioplasty and bypass in octogenarians. Am J Cardiol 1991;68:1316-20.

84. Kern MJ, Deligonul U, Galan K, et al. Percutaneous transluminal coronary angioplasty in octogenarians. Am J Cardiol 1988;61:457-8.

85. OâKeefe JH Jr, Sutton MB, McCallister BD, et al. Coronary angioplasty versus bypass surgery in patients >70 years old matched for ventricular function. J Am Coll Cardiol 1994;24:425-30.

86. Tsai TP, Nessim S, Kass RM, et al. Morbidity and mortality after coronary artery bypass in octogenarians. Ann Thorac Surg 1991;51:983-6.

87. Mohan R, Amsel BJ, Walter PJ. Coronary artery bypass grafting in the elderly ö a review of studies in patients older than 64, 69 or 74 years. Cardiology 1992;80:215-25.

88. Davies MJ, Thomas AC. Thrombosis and acute coronary artery lesions in sudden cardiac ischemic death. N Engl J Med 1984;310:1137-40.

89. Margolis JR, Mehtas S, Litvack F, Untereker WJ, Goldenberg T and the ELCA Registry Investigators. Results of the first 5000 patients treated with Excimer laser coronary angioplasty. J Am Coll Cardiol 1994;(Suppl):448A. (Abst)

90. Topol EJ, Lea F, Pinkerton CA, et al. A comparison of directional atherectomy with coronary angioplasty in patients with coronary artery disease. N Engl J Med 1993;329:221-7.

91. Umans VAWM, Keane D, Foley D, Boersma E, Melkert R, Serruys PW. Optimal use of directional coronary atherectomy is required to ensure long-term angiographic benefit: a study with matched procedural outcome after atherectomy and angioplasty. J Am Coll Cardiol 1994;24:1652-9.

92. Leon MB, Kuntz RE, Popma JJ, et al. Acute angiographic, intravascular ventrasound and clinical results of directional atherectomy in the Optimal Atherectomy Restenosis Study. J Am Coll Cardiol 1995;(Suppl):137A. (Abst)

93. Virmani R, Farb A. Rotational coronary atherectomy. J Am Coll Cardiol 1991;18:1702-3.

94. Vandormael M, Reifart N, Preusler W, et al. Comparison of Excimer laser angioplasty and rotational atherectomy with balloon angioplasty for complex lesions: ERBAC study final results. J Am Coll Cardiol 1994;(Suppl):57A. (Abst)

95. de Feyter PJ, van Suylen RJ, de Jaegere PPT, et al. Balloon angioplasty for the treatment of lesions in saphenous vein bypass grafts. J Am Coll Cardiol 1993;21:1539-50.

96. Vrolix M, Piessens J. Usefulness of the Wiktor stent for treatment of threatened or acute closure complicating coronary angioplasty. Am J Cardiol 1994;73:737-41.

97. Carrozza JP, Kuntz RE, Levine MJ, et al. Angiographic and clincial outcome of intracoronary stenting: immediate and long-term results from a large single-centre experience. J Am Coll Cardiol 1992;20:328-37.

98. Fischman DL, Leon MB, Baim DS, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. N Engl J Med 1994;331:486-501.

99. Serruys PW, de Jaegere P, Kiemeneij F, et al. A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331:489-95.

100. Wong SC, Popma JJ, Pichard AD, et al. Comparison of clinical and angiographic outcomes after saphenous vein graft angioplasty using coronary versus ãbiliaryä tubular slotted stents. Circulation 1995;91:339-50.

101. Nakamura S, Colombo A, Gagione A. Intracoronary ultrasound observations during stent implantation. Circulation 1994;89:2026-34.

102. Goldberg SL, Colombo A, Nakamura S, Almagor Y, Maiello L, Tobes JM. Benefit of intracoronary ultrasound in the deployment of Palmaz-Schatz stent. J Am Coll Cardiol 1994;24:989-95.

103. Colombo A, Hall P, Nakamura S. Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. Circulation 1995;91:1676-88.

104. Buchanan MR, Brister SJ. Antithrombotics and the lipoxygenase pathway. In: Herman AG, ed. Antithrombotics. Boston: Kluwer Academic Publishers, 1991:157-79.

105. Lytle BW, Cosgrove D, Loop FD. Future implications of current trends in bypass surgery. Cardiovasc Clin 1991;21:265-78.

106. Plante S, Strauss BH, Goulet G, Watson RK, Chisholm RJ. Reuse of balloon catheters for coronary angioplasty: a potential cost-saving strategy? J Am Coll Cardiol 1994;24:1475-81.

107. Grines CL, Browne KF, Marco J, et al. A comparison of immediate angioplasty with thrombolytic therapy for acute myocardial infarction. N Engl J Med 1993;328:673-9.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 2: Revascularization strategies in patients with stable angina pectoris

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Evidence concerning the efficacy of revascularization in coronary artery disease (CAD) began with the randomized trials of the 1970s comparing surgery with medical therapy. From these trials, subgroups of patients were identified who appeared to benefit most from bypass surgery, and these lessons have influenced surgical practice since that time. The initial patients treated with angioplasty by Andreas Gruentzig had single vessel disease, were severely symptomatic and were offered percutaneous transluminal coronary angioplasty (PTCA) as an alternative to surgery (1). There is evidence, at least in the United States, that the procedure is now being used predominantly in patients who would formerly have been treated medically (2). This procedure continued to mature and evolve in the 1980s with monitoring by registries and case control analyses, but without the guidance from large randomized trial data. More recently randomized trial data have become available, comparing the efficacy of surgery with that of PTCA in restricted patient subgroups where both surgery and angioplasty are thought to be reasonable options. This process of validation is important before there is further movement away from a strategy of medical therapy in most patients with CAD.

2.1 RANDOMIZED TRIALS OF MEDICAL THERAPY AND SURGERY

Coronary artery bypass grafting (CABG) has been analyzed and scrutinized probably more than any other surgical procedure of the past 30 years. The most significant trials were the Veterans Administration Study (3,4), the CASS (Coronary Artery Surgery Study) (5,6) and the

European Cooperative Surgery Trial (7,8). The conclusions of these trials were consistent: compared with medical therapy, CABG was demonstrated to improve survival in patients with left main disease, triple vessel disease and in severe double vessel CAD that involved the proximal left anterior descending (LAD) artery. This survival benefit was most striking in patients with left ventricular dysfunction. No survival benefit was seen in other patients with double vessel disease and patients with single vessel disease.

The first major criticism of these trials is that they were highly selective, with a patient profile that differs significantly from clinical practice of today. Table 2.1 summarizes of baseline characteristics from a recent meta-analysis of the major randomized trials (9). The majority of patients had good ventricular function, only 35% had Canadian Cardiovascular Society class III or IV angina, and only 7% were over 60 years of age. Finally, females were grossly underrepresented, accounting for 3.2% of the study population.

The second criticism is that only 47.4% of patients were on beta-blockers and 3.2% were on antiplatelet drugs, a practice quite different from optimal medical strategies of 1995.

Crossover rates from the medical to the surgical group in the randomized trials were uniformly high, averaging 25% at five years and 40% at 10 years (Table 2.2). The crossover rates were influenced by the extent of disease, the presence of more severe angina and a positive exercise test, but were not influenced by the presence of left ventricular dysfunction.

Overall risk reduction of patients randomized to surgery was consistent in all the major trials, averaging 39% at five years, 32% at seven years and 17% at 10 years. Several subgroups were analyzed and, in general, patients with more extensive disease showed the greatest risk reduction benefit. In view of the very high crossover rate from medical to surgical therapy, these trials most likely underestimate the absolute benefit of CABG on survival. This benefit persisted even after patients with left main disease were excluded from the analysis. The declining risk reduction over time likely represents late graft occlusion and progression of native CAD (9).

Changes in medical and surgical management known to influence the natural history of CAD patients have occurred over the past two decades. These changes include lipid-lowering agents, more effective antianginal and antiplatelet drugs, newer cardioplegia techniques and the use of arterial conduits. Would a medicine versus surgery trial conducted today lead to different conclusions? The answer is not clear, but it is reasonable to hypothesize that the surgical advantage may even be larger today (10). The secondary prevention benefits of aggressive lipid lowering would likely affect surgical and medical groups equally (11).

Given the selectivity of the randomized trials highlighted above, has the promise of the clinical trials been fulfilled when applied to a normal clinical environment? Information from the Duke Cardiovascular Disease Database (Duke University, North Carolina) suggests that the conclusions are clinically relevant. Between March 1984 and August 1990, 17,309 consecutive patients were referred to the Duke Heart Center in Durham, North Carolina for initial cardiac catheterization for evaluation of suspected ischemic heart disease. Nonrandomized treatment decisions and outcome were prospectively monitored to calculate hazard ratios of surgical and medical treatment for a variety of anatomical subsets. For this analysis 7710 patients were excluded for the following reasons: absence of significant (greater than 75% diameter) stenosis in at least one major epicardial coronary segment (n=5817); greater than 75% of left main stenosis (n=691); significant (3+ to 4+) ischemic mitral regurgitation (n=422); prior PTCA (n=253); and prior CABG (n=527). Patients with primary valvular, congenital or cardiomyopathic disease were also excluded. Thus, the final study population consisted of 9263 patients with significant CAD comprising all eligible patients with stable angina, progressive angina, unstable angina, postinfarction angina, an acute evolving myocardial infarction (MI) or a recent MI. The hazard ratio of CABG compared with medical treatment and its confidence intervals were all significantly less than unity in patients with triple vessel disease and in patients with double vessel disease with proximal LAD involvement (12) (Figure 2.1). The major limitation of this large observational database to this discussion of revascularization in stable angina is that only 27% and 19% of medically and surgically treated groups, respectively, had stable angina.

TABLE 2.1

Summary of patient characteristics in randomized trials (n=2649)

Characteristics	Patients (%)
Age distribution (years)	
<40	8.5
41-50	38.2
51-60	46.0
>60	7.3
Ejection fraction	
<40	7.2
40-49	12.5
50-59	28.0
>60	52.3
Male	96.8
Severity of angina	
None	11.2
Class I or II*	53.8
Class III or IV*	35.0
History	
Myocardial infarction	59.6
Hypertension	26.0
Heart failure	4.0
Diabetes	9.6
Smoking history	83.5
Current smoker	45.5
ST depression >1 mm	
Resting	9.9
Exercise	70.5
Drugs at baseline	
Beta-blockers	47.4
Antiplatelets	3.2
Digitalis	12.9
Diuretics	12.6
Number of vessels diseased	
center main	6.6
One vessel	10.2
Two vessels	32.4
Three vessels	50.6

Location of disease	
Proximal LAD	59.4
LAD diagonal	60.4
Circumflex	73.8
Right coronary artery	81.6

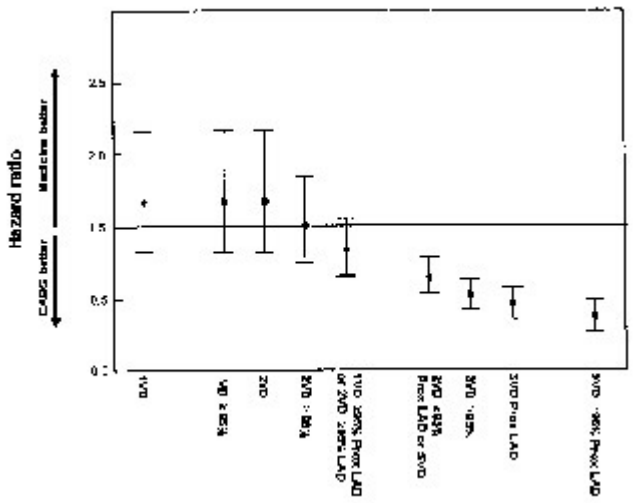
**Canadian Cardiovascular Society class. LAD Left anterior descending artery. Data from reference 9*

TABLE 2.2

Crossover rates from medical to surgical therapy in randomized trials

	5-year (%)	7-year (%)	10-year (%)
Overall	25	33	41
Veterans Administration	25	34	44
European	28	38	43
CASS	25	33	40

CASS Coronary Artery Surgery Study. Data from reference 9



2.2 NONRANDOMIZED TRIALS OF SURGERY VERSUS ANGIOPLASTY

Nonrandomized comparisons of PTCA versus CABG are outlined in Table 2.3. These data indicate that early and late mortality are comparable between PTCA and CABG, although

CABG patients were older and had more significant CAD (more triple vessel disease and lower ejection fractions) (1).

2.3 SURGERY-ANGIOPLASTY RANDOMIZED TRIALS ö MORTALITY AND MYOCARDIAL INFARCTION DATA

Results from the six major randomized comparisons between surgery and angioplasty in multivessel disease are summarized in Table 2.5: EAST (Emory Angioplasty versus Surgery Trial); GABI (German Angioplasty Bypass surgery Investigation); RITA (Randomized Intervention Treatment of Angina); ERACI (Estudio Randomizado Argentino de Angioplastia vs CIrugia); CABRI (Coronary Artery versus Bypass Revascularization Investigation); and BARI (Bypass Angioplasty Revascularization Investigation). Patients for these trials were selected on the basis of their suitability for either PTCA or CABG. Exclusion criteria for all studies included left main CAD, previous CABG or previous PTCA.

TABLE 2.3

Nonrandomized comparisons of CABG versus PTCA

Trial (reference)	Patients (n)	Follow-up	Extent of disease CABG vs PTCA (%)	Baseline CABG vs PTCA (%)	End-points CABG vs PTCA
Finci et al (30)	CABG (80) PTCA (80)	12-16 months	2VD: 39 vs 80 3VD: 61 vs 20	Prior MI: 64 vs 44 Hypertension: 43 vs 20	Mortality: equal NYHA I: 89 vs 60 Angina-free: 89 vs 55
Hochberg et al (31)	CABG (125) PTCA (125)	3 years	SVD: 70 vs 70 2VD: 30 vs 30	EF: 0.48 vs 0.54 P=0.003	Mortality: 2.5 vs 7 NYHA I/II: 92 vs 63 NYHA III/IV: 4 vs 12
Vacek et al (32)	CABG (134) PTCA (152)	110-134 weeks	2VD: 32 vs 94 3VD: 68 vs 6	EF: 0.48 vs 0.53 P=0.002	Mortality: 14 vs 10 MI: 2 vs 4 Recatheterization: 10 vs 49
Hartz et al (33)	CABG (71,243) PTCA (25,423)	1 month and 1 year	1VD: 7.6 vs 44.2 2VD: 23.8 vs 36.3 3VD: 68.7 vs 19.5	CABG older with more CHF, diabetes and prior MI	Mortality: Early: 6.4 vs 3.8 Late: 11.6 vs 8.2
Weintraub et al (27,34)	CABG (454) PTCA (415)	5 years	All 2VD	Age: 60 vs 57 years Diabetes: 15 vs 10 Prior MI: 54 vs 44	Mortality: 11 vs 7 RR: 7 vs 43
O'Keefe et al (35)	CABG (100) PTCA (100)	5 years	3VD: 88 vs 85	CCS Class III/IV: 82 vs 63 P<0.001	Mortality: 24 vs 33 Event-free survival: 78 vs 48 RR: 0 vs 40
Myler et al (36)	CABG (105) PTCA (77)	5 years	All 3VD	Age: 62 vs 58 years P<0.01	Mortality: 13.4 vs 10 No angina: 85.6 vs 81.3 RR: 5.2 vs 56

1VD Single vessel disease; 2VD Double vessel disease; 3VD Triple vessel disease; CABG Coronary artery bypass graft; CCS Canadian Cardiovascular Society; CHF Congestive heart failure; EF Ejection fraction; MI Myocardial infarction; NYHA New York Heart Association; PTCA Percutaneous transluminal coronary angioplasty; RR Repeat revascularization. Data from reference 1

TABLE 2.4

Selected details of RITA, GABI, EAST and ERACI trials

CABG (n)	PTCA (n)	Percentage of screened patients randomized	Length of follow-up (years)	Female (%)	Stable angina CCS£ II (%)	Total occlusions allowed	PTCA success (%)	MVD (%)	
RITA	501	510	4.8	2.5	19	35	Yes	87	55
GABI	177	182	4	1	20	N/A	No	86	100
EAST	194	198	8	3	25	20	No	88	100
ERACI	64	63	9	1	15	15	Yes	51	100
CABRI	513	541	4.6	1	22	37	N/A	N/A	99
BARI	914	915	7.3	5	26	13	37	88	100

BARI Bypass Angioplasty Revascularization Investigation; CABG Coronary artery bypass graft; CABRI Coronary Angioplasty versus Bypass Revascularization Investigation; CCS Canadian Cardiovascular Society; EAST Emory Angioplasty versus Surgery Trial; ERACI Estudio Randomizado Argentino de Angioplastia vs CIrugia (Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease); GABI German Angioplasty Bypass surgery Investigation; MVD Multivessel disease; N/A Not available; PTCA Percutaneous transluminal coronary angioplasty; RITA Randomized Intervention Treatment of Angina

As with the earlier surgery and medical therapy trials, a low 4% to 9% of screened patients were eventually randomized, again raising concerns about how applicable the trial results would be to clinical practice. The trials had a low incidence of stable angina pectoris (Canadian Cardiovascular Society [CCS] class II or less); only 15% to 25% of patients randomized were female, the duration of follow-up was short and only the RITA trial randomized patients greater than 75 years of age. In trials that reported left ventricular ejection fraction, patients with left ventricular dysfunction were, by and large, excluded from randomization. (Table 2.4).

In-hospital and follow-up mortality were quite low and similar for the PTCA and the CABG groups, although a higher percentage of patients suffered stroke or acute MI in the surgical

group during the initial hospitalization (6.5% versus 3.7%). (Table 2.5). Because many high risk patient subsets were excluded from randomization and the number of randomized patients enrolled was only a small percentage of the patients being treated, these data are not sufficient to make firm conclusions about the relative safety of the two approaches. In addition, the longer term comparative effects of the two revascularization strategies are unknown.

Subgroup analysis from the BARI trial suggest a significant mortality benefit with surgery for diabetics requiring medical control of their diabetes. The five-year mortality among diabetics treated with angioplasty and surgery was 35% and 19%, respectively.

2.4 ANGIOPLASTY - THE MULTIPLE PROCEDURE ISSUE

From available randomized and nonrandomized data we can conclude that, in some patients with multivessel CAD, the short term safety of PTCA is similar to that of CABG. However, PTCA patients appear to have less freedom from angina, require more antianginal medications and undergo more repeat interventions than surgically treated patients in the long term. Combined data from RITA, GABI, ERACI and EAST, at follow-up ranging from one to three years, indicate that 67.1% of PTCA and 79.6% of surgery patients are asymptomatic (15-18).

As shown in Table 2.5, over one to three years' follow-up, nonprotocol bypass surgery was performed in 1% and 19.9% of patients randomized to surgery and angioplasty, respectively, and nonprotocol PTCA was performed in 4.4% and 20.3% of patients randomized to surgery and angioplasty, respectively. Use of follow-up diagnostic angiography was also substantially higher in the angioplasty group (15). These data raise resource utilization and patient inconvenience concerns, but a balanced view is needed. If revascularization decisions are to be made on the basis of this apparent unfavourable balance, given equivalent morbidity and mortality data, a broader view of the issues is necessary. In Table 2.6, the relative resource utilization and patient inconvenience advantages of surgery and angioplasty are summarized as specific data from the randomized trials.

By current patterns of practice, the lengths of stay for surgery and angioplasty shown in Table 2.6 are excessive but the relative lengths are unchanged. Average lengths of stay for surgery and angioplasty in 1995 are approximately five to eight days and one to three days, respectively. As this table illustrates, the issues of relative resource utilization and patient inconvenience are complex with no obvious reason to choose one procedure over the other in all cases. Where both revascularization options are appropriate in a given case, the process of informed consent should include full disclosure of the possible short and long term consequences of each decision.

TABLE 2.5

Selected outcome results of RITA, GABI, EAST and ERACI trials

Trial	Group	n	In-hospital events: n (%)				Cumulative events at follow-up: n (%)			
			Death	MI or stroke	CABG	PTCA	Death	MI	CABG	PTCA
RITA	CABG	501	6 (1.2)	17 (3.4)	N/A	N/A	18 (3.6)	26 (5.2)	4 (0.8)	21 (4.2)
	PTCA	510	4 (0.8)	19 (3.7)	29 (5.7)	5 (1.0)	16 (3.1)	34 (6.7)	96 (18.8)	93 (18.2)
GABI	CABG	177	4 (2.5)	15 (8.5)	2 (1.1)	1 (0.6)	9 (5.1)	13 (7.3)	2 (1.1)	7 (4.0)
	PTCA	182	2 (1.1)	4 (2.2)	15 (8.2)	5 (2.7)	4 (2.2)	7 (3.8)	41 (22.5)	50 (27.4)
AST	CABG	194	2 (1.0)	23 (11.9)	0	0	12 (6.2)	38 (19.6)	1 (0.5)	13 (6.7)
	PTCA	198	2 (1.0)	7 (3.5)	20 (10.1)	0	14 (7.1)	29 (14.6)	42 (22)	41 (20.7)
ERACI	CABG	64	3 (4.6)	6 (9.4)	0	1 (1.5)	0	1 (1.8)	2 (3.2)	0
	PTCA	63	1 (1.5)	5 (7.9)	1 (1.5)	0	2 (3.9)	2 (3.2)	11 (18)	9 (16)
CABRI	CABG	513	9 (1.9)	N/A	N/A	N/A	14 (2.7)	18 (3.5)	4 (0.8)	14 (2.7)
	PTCA	541	7 (1.3)	N/A	N/A	N/A	21 (3.9)	27 (4.9)	85 (15.7)	113 (21)
BARI	CABG	914	12 (1.3)	48 (5.4)	1 (0.1)	0	111 (10.7)	107 (11.7)	6 (1)	63 (7)
	PTCA	915	10 (1.1)	21 (2.3)	92 (10.2)	31 (3.4)	131 (13.7)	99 (10.9)	283 (31)	311 (34)
Total	CABG	2326	36 (1.5)	109 (6)	3 (0.2)	2 (0.1)	164 (8.3)	203 (8.7)	19 (0.8)	118 (5)
	PTCA	2409	26 (1.1)	56 (3)	157 (8.4)	41 (2.2)	188 (7.8)	198 (8.2)	558 (23)	617 (25)

BARI Bypass Angioplasty Revascularization Investigation; CABG Coronary artery bypass graft; CABRI Coronary Angioplasty versus Bypass Revascularization Investigation; EAST Emory Angioplasty versus Surgery Trial; ERACI Estudio Randomizado Argentino de Angioplastia vs CIrugia (Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease); GABI German Angioplasty Bypass surgery Investigation; MI Myocardial infarction; N/A Not available; PTCA Percutaneous transluminal coronary angioplasty; RITA Randomized Intervention Treatment of Angina

The controversy that exists on the subject of multiple procedures is best described by the plight of a young patient with triple vessel disease or double vessel disease with proximal LAD involvement. One side would argue that surgery with the use of multiple arterial grafts would provide a reliable long term solution to the patient's problem without the stress, disruption and travel commitments associated with multiple hospital admissions. This side would also contend that CAD progression is usually a proximal phenomenon likely occurring within coronary segments that are bypassed. The other side would contend that only arterial grafting to the LAD has demonstrated long term benefit in the average surgical centre at this point; therefore, known graft attrition rates will make the need for reoperation quite likely in the young patientâs lifetime (19). Further, where lesions are suitable, stenting has a low restenosis rate and appears to result in lower procedural mortality and morbidity than with surgery (20,21). The recurrent procedures seen following angioplasty are usually required because of restenosis and therefore are confined to the first four to six months and are not an ongoing pattern (22). With disease progression, preservation of the native coronary artery could better position the patient for dealing with the new lesions as they appear. The argument on both sides is sound and the right course of action is not clear.

There are now randomized data indicating that the use of primary stenting is associated with a 50% reduction in clinical restenosis rates with reduction in the need for repeat procedures by a similar amount (20, 21). If the promise of these trials can be translated into clinical reality, the impact on the issue of recurrent procedures with angioplasty would be striking.

2.5 COMPLETENESS OF REVASCULARIZATION AND PROCEDURE SELECTION ISSUES

Retrospective analyses of surgical outcome with multivessel disease clearly showed that the degree to which it was possible to revascularize a patient strongly influenced outcome (23-25). Patients with complete revascularization had lower procedural complication rates and better symptom control in the long term. Because it is frequently not possible to completely revascularize a patient with multivessel disease by angioplasty due to the presence of complex anatomy, in particular chronic total occlusions, the appropriateness of angioplasty in

multivessel disease has been called into question. Others have questioned this conclusion, demonstrating that as long as the patient has been Îfunctionally revascularizedâ, that is, where all-important regions of ischemia are revascularized, outcome is favourable (25-27). Regions that are not revascularized would be regions of prior infarction; small regions with diffusely diseased or small vessels; or regions with excellent collateral support and no evidence of ischemia.

Several of the randomized trials allowed incomplete revascularization as long as 'functional Revascularization' was achieved. In the ERACI trial, event-free survival curves for anatomically complete and functionally complete revascularization groups were the same (18).

2.6 RANDOMIZED ANGIOPLASTY VERSUS MEDICINE TRIALS

There is only one reported trial comparing medical therapy with PTCA in single vessel CAD. The ACME (Angioplasty Compared to MEdicine) trial randomized 212 males to single vessel PTCA or to medical therapy. All patients had stable angina and a positive exercise stress test or a previous MI. PTCA was successful in only 80% of patients. At six months of follow-up the PTCA group were able to increase total exercise duration more than the medical group (2.1 mins versus 0.5 mins, P<0.0001) and more often had complete relief of angina than medically treated patients (64% versus 46%). However, when a composite end-point of freedom from death, MI, PTCA or CABG at six months is used, there was a significant trend favouring the medically treated group. Additionally, cardiac hospital days totalled 324 for PTCA patients compared with 101 days for the medical group (28).

TABLE 2.6

Relative resource utilization and patient convenience issues with angioplasty and surgery

	Angioplasty	Bypass surgery
Length of stay with initial admission (15,37)	4-5 days	12-19 days
Nonend-point morbidity (15,17,18,37)	Stroke (0.3%) pneumonia (1.1%) transfusion (2.8%)	Stroke(1.4%) pneumonia (9.6%) transfusion (5.6%) repeat thoracotomy (3.4%)
Readmissions for angiography and repeat revascularization, assuming 2 days for catheterization, 4.5 days for PTCA and 15 days for surgery	4.5 days per enrolled patient, assuming catheterization in 31.2% (14), PTCA in 20.3% and CABG in 19.9% (Table 2.4)	0.3 days per enrolled patient, assuming catheterization in 7.8% (14), PTCA in 4.4% and CABG in 1% (Table 2.4)
Percentage *not* working at 1 month and 6 months (15)	54% and 31%, respectively	79% and 30%, respectively

CABG Coronary artery bypass surgery; PTCA Percutaneous transluminal coronary angioplasty

2.7 RECOMMENDATIONS

The clinical recommendations that follow are presented with prior emphasis of several important points, as follows.

Local revascularization skill and experience may vary. Although decisions are influenced by the 'lessons' in the literature, final decisions are reached only after consultation by the attending cardiologist with local surgeons and interventional cardiologists. Hence, the recommendations that follow are for 'referral' to one form of revascularization or another. In this referral process the surgeons and interventional cardiologists will decide whether, in their hands, the patient is suitable for the requested procedure. Information on local expertise and clinical results in coronary stenting and arterial grafting in a variety of high risk patient groups should be available to all involved in the decision-making process.

Many recommendations are based on the strength of randomized trials two decades old. Nevertheless, they are trials that have withstood the test of time. Patients included in these trials were highly selected and may not be representative of many of the patients that are referred for revascularization in 1995. Caution should be exercised in overapplying these data to groups excluded from these trials, for example, elderly women.

In 1995, the issue of patient expectations requires reevaluation. Many patients do not want to have CCS class I or II angina on multiple medications when angioplasty is available that may render them asymptomatic on few medications. Evidence suggests, however, that pursuit of this goal carries a cost. Published clinical trials indicate that this quest frequently entails multiple procedures, and the number of medications is often not reduced in the long run as expected. Whether the cost of the 'symptom- and drug-free' goal has decreased significantly in the modern Îstent eraâ remains unconfirmed.

Interventional cardiology is undergoing major changes, particularly in the area of stenting. Indeed, surgical techniques are also improving. Randomized trials are available that confirm significant reduction in acute complications and restenosis rates with stenting, changes that may dramatically alter revascularization decision-making. Trials comparing stenting with surgery and medical treatment strategies are not available, but progress in this area should be monitored closely. Until these trial results are available, the following recommendations are felt to be reasonable.

Where both angioplasty and surgery options are supported by the literature, the choice will depend on lesion anatomy, probability of success, risk of major complications and patient preference.

2.7.1 Patients with unprotected left main CAD should be referred for revascularization. The preferred revascularization method is surgery.

Class: A

Level: I

2.7.2 Patients with triple vessel CAD and left ventricular dysfunction should be referred for revascularization. Bypass surgery is generally the most appropriate revascularization method.

Class: A

Level: I

Patients with suitable lesions could be considered for angioplasty with appropriate consultation and informed consent.*

Class: B

Levels: II, III and IV

2.7.3 Patients with double vessel CAD, including proximal LAD, should be referred for revascularization. Bypass surgery is an appropriate method of revascularization.

Class: A

Level: I

Patients with suitable lesions could be considered for angioplasty with appropriate consultation and informed consent.*

Class: B

Levels: II, III and IV

2.7.4 Patients with double vessel disease, not involving the proximal LAD, should be referred for revascularization when the constraints of medical management are not acceptable. Both angioplasty and surgery are appropriate methods of revascularization.

Class: B

Levels: II, III and IV

2.7.5 Patients with single vessel disease should be referred for revascularization when the constraints of medical management are not acceptable. Both angioplasty and surgery are appropriate methods of revascularization, although angioplasty is usually preferred.

Class: B

Level: II

2.7.6 Patients with an isolated CABG stenosis should be referred for stenting. When diffuse disease is present in old saphenous vein grafts, however, repeat bypass surgery should be considered.

Class: B

Levels: II, III and IV (29)

*Patients suitable for a nonsurgical approach in these categories would be best served by primary stenting wherever possible to maintain competitive procedure morbidity and mortality rates and to maintain the need for recurrent procedures to an acceptable level.

REFERENCES

1. arisi AF, Burtt DM. Revascularization procedures in the treatment of single-vessel coronary disease. Coron Artery Dis 1993;4:1053-60.

2. Gersh BJ. Coronary revascularization in the 1990s: A cardiologistâs perspective. Can J Cardiol 1994;10:661-70.

3. Eleven-year survival in the Veterans Administration randomized trial of coronary bypass surgery for stable angina: The Veterans Administration Coronary Artery Bypass Surgery Cooperative Study Group. N Engl J Med 1984;311:1333-9.

4. Takaro T, Peduzzi P, Detre KM, et al. Survival in subgroups of patients with left main coronary artery disease. Veterans Administration cooperative study of surgery for coronary arterial occlusive disease. Circulation 1982;66:14-22.

5. Coronary Artery Surgery Study (CASS): a randomized trial of coronary artery bypass surgery. Survival data. Circulation 1983;68:939-50.

6. Passamani E, Davis K, Gillespie M. A randomized trial of coronary artery bypass surgery: Survival of patients with a low ejection fraction. N Engl J Med 1983;312:26.

7. Varnauskas E, European Coronary Surgery Study Group. Twelve-year follow-up of survival in the randomized European Coronary Surgery Study. N Engl J Med 1988;319:332-7.

8. Prospective randomized study of coronary artery bypass surgery in stable angina pectoris: a progress report on survival. Circulation 1982;65:67-71.

9. Yusuf S, Zucker D, Peduzzi P, et al. Effect of coronary artery bypass graft surgery on survival: overview of 10-year results from randomised trials by the Coronary Artery Bypass Graft Surgery Trialists Collaboration. Lancet 1994;344:563-70.

10. Pryor DB, Harrell FE Jr, Rankin S, et al. The changing survival benefits of coronary revascularization over time. Circulation 1987;76:V13-21.

11. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: The Scandinavian Simvastatin Survival Study. Lancet 1994;344:1383-9.

12. Mark DB, Nelson CL, Califf RM, et al. Continuing evolution of therapy for coronary artery disease: initial results from the era of coronary angioplasty. Circulation 1994;89:2015-25.

13. Bypass Angioplasty Revascularization (BARI) Investigators. Comparison of coronary bypass surgery with angioplasty in patients with multivessel disease. N Engl J Med 1996;335:217-25.

14. CABRI trial investigators. Five-year results of CABRI (Coronary Angioplasty versus Bypass Revascularization Investigation). Lancet 1995;346:1179-84.

15. Coronary angioplasty versus coronary artery bypass surgery: The Randomized Intervention Treatment of Angina (RITA) trial. Lancet 1993;341:573-80.

16. King SB 3rd, Lembo NJ, Weintraub WS, et al. A randomized trial comparing coronary angioplasty with coronary bypass surgery. Emory Angioplasty versus Surgery Trial (EAST) [see comments]. N Engl J Med 1994;331:1044-50.

17. Hamm CW, Reimers J, Ischinger T, Rupprecht HJ, Berger J, Bleifeld W. A randomized study of coronary angioplasty compared with bypass surgery in patients with symptomatic multivessel coronary disease. German Angioplasty Bypass surgery Investigation (GABI) [see comments]. N Engl J Med 1994;331:1037-43.

18. Rodriguez A, Boullon F, Perez-Balino N, Paviotti C, Liprandi MI, Palacios IF. Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease (ERACI): in-hospital results and 1-year follow-up. J Am Coll Cardiol 1993;22:1060-7.

19. Weintraub WS, Jones EL, Craver JM, Guyton RA. Frequency of repeat coronary bypass or coronary angioplasty after coronary artery bypass surgery using saphenous venous grafts. Am J Cardiol 1994;73:103-12.

20. Fischman DL, Leon MB, Baim DS, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. N Engl J Med 1994;331:486-501.

21. Serruys PW, de Jaegere P, Kiemeneij F, et al. A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331:489-95.

22. de Feyter PJ, Keane D, Deckers JW, de Jaegere P. Medium- and long-term outcome after coronary balloon angioplasty. Prog Cardiovasc Dis 1994;36:385-96.

23. Jones EL, Craver JM, Guyton RA, Bone DK, Hatcher CR Jr. Importance of complete revascularization in performance of the coronary bypass operation. Am J Cardiol 1983;51:7-12.

24. Lawrie GM, Morris GC Jr, Silvers A, et al. The influence of residual disease after coronary bypass on the 5-year survival rate of 1274 men with coronary artery disease. Circulation 1982;66:717-23.

25. Bell MR, Gersh BJ, Schaff HV, et al. Effect of completeness of revascularization on long-term outcome of patients with three-vessel disease undergoing coronary artery bypass surgery. A report from the Coronary Artery Surgery Study (CASS) Registry. Circulation 1992;86:446-57.

26. Wohlgelernter D, Cleman M, Highman HA, Zaret BL. Percutaneous transluminal coronary angioplasty of the 'culprit lesion' for management of unstable angina pectoris in patients with multivessel coronary artery disease. Am J Cardiol 1986;58:460-4.

27. Weintraub WS, King SB III, Jones EL, et al. Completeness of revascularization after coronary angioplasty and coronary surgery: different strategies, different results. J Am Coll Cardiol 1993;21:73A. (Abst)

28. Parisi AF, Folland ED, Hartigan P. A comparison of angioplasty with medical therapy in the treatment of single-vessel coronary artery disease. N Engl J Med 1992;326:10-6.

29. Morrison DA, Crowley ST, Veerakul G, Barbiere CC, Grover F, Sacks J. Percutaneous transluminal angioplasty of saphenous vein grafts for medically refractory unstable angina. J Am Coll Cardiol 1994;23:1066-70.

30. Finci L, Von Segesser L, Meier B, et al. Comparison of multivessel coronary angioplasty with surgical revascularization with both internal mammary arteries. Circulation 1987;76:V1-5.

31. Hochberg MS, Gielchinsky I, Parsonnet V, Hussain SM, Mirsky E, Fisch D. Coronary angioplasty vs coronary bypass. Three year follow-up of a matched series of 250 patients. J Thorac Cardiovasc Surg 1989;97:496-503.

32. Vacek JL, Rosamond TL, Stites HW, et al. Comparison of percutaneous transluminal coronary angioplasty versus coronary artery bypass grafting for multivessel coronary artery disease. Am J Cardiol 1992;69:592-7.

33. Hartz AJ, Kuhn EM, Pryor DB, et al. Mortality after coronary angioplasty and coronary artery bypass surgery (the National Medicaire experience). Am J Cardiol 1992;70:179-85.

34. Weintraub WS, King SB III, Jones EL, Douglas JS. Coronary angioplasty in patients with two-vessel coronary artery disease. Am J Cardiol 1993;71:511-7.

35. OâKeefe JH Jr, Allan JJ, McCallister BD, et al. Angioplasty versus bypass surgery for multivessel coronary artery disease with left ventricular ejection fractions < 40%. Am J Cardiol 1993;71:897-901.

36. Myler RK, Shaw RE, Baciewicz PA, et al. Five-year comparison of triple vessel revascularization: coronary bypass surgery versus balloon angioplasty. J Am Coll Cardiol 1993;21:73A. (Abst)

37. Goy JJ, Eeckhout E, Burnand B, et al. Coronary angioplasty versus left internal mammary artery grafting for isolated proximal left anterior descending artery stenosis. Lancet 1994;343:1449-53.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 3: Unstable angina and no-Q wave infarction

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Acute coronary syndromes account for the vast majority of hospital admissions of patients with ischemic heart disease. Unstable angina pectoris is the most common of the acute syndromes. Its dramatic, abrupt presentation disrupts the lives of patients and carries with it a sense of diagnostic and treatment urgency. This chapter reviews concepts that direct diagnostic and treatment decisions in unstable angina, from basic pathophysiology to clinical trial data and the technical aspects of revascularization. In the midst of the disruption and urgency, order is possible.

3.1 DEFINITION OF UNSTABLE ANGINA

The essence of unstable angina is deterioration in a previously stable clinical pattern. This deterioration can be expressed as new onset angina, prolonged pain, pain at rest or an acceleration of a previously stable pain pattern, usually within the previous two months. The two classification systems that have been studied most closely are those of Braunwald (1) and, more recently, that of Rizik (2). The Braunwald classification, although used in Europe, has not been widely adopted in the United States and Canada. Although some secondary reviewers urge caution in this regard, the consensus members encourage use of these classification systems to improve communication and research in this area.

In the Braunwald definition, four categories are described separately:

Etiology: A - Secondary (an unstable pain pattern that occurs secondary to other events that suddenly increase myocardial oxygen demand without new coronary flow limitations, e.g., anemia, tachycardia, hypertensive crises); B - Primary (a pain pattern change initiated by a change in coronary flow dynamics); C - Postinfarction angina (recurrent pain within two weeks after a myocardial infarction [MI]).

Circumstances: I - No pain at rest but a decrease in the effort needed to induce pain; II - Pain at rest, but not within the past 48 h; III - Pain at rest within the past 48 h.

Treatment: 1 - Less than maximal medical therapy; 2 - Maximal tolerated medical therapy; 3 - Pain requiring the use of intra-aortic balloon assist devices or intravenous nitroglycerine.

Electrocardiogram: Presence or absence of ST depression or T wave inversion in two or more continuous leads during pain.

The electrocardiogram (ECG) is important in the evaluation of patients with unstable angina because it can add specificity and prognostic information. The recent classification system proposed by Rizik et al (2) highlights the prognostic as well as diagnostic importance of ECG changes. The highest degree of specificity is associated with reversible ECG changes with pain episodes. Resting changes are less specific but ST segment depression or T wave inversion not explained by other factors have prognostic value and favour more aggressive investigation. The review by Farhi and Fuster (3) further supports the position that the ECG can be used to identify a high risk group with unstable angina. The presence of reversible ST segment depression with pain and the presence of ST depression and widespread T wave inversion on a baseline ECG are given special significance in this regard.

The Canadian Cardiovascular Society classification of angina (4) is used in stable and unstable syndromes to describe the level of activity required to produce pain. Class IV refers to pain at rest. Class IV has been subdivided into three groups based on the intensity of concurrent medical therapy (5):

- IV-A - Pain resolved with intensified medical therapy, now stable on oral medication;

- IV-B - On optimal oral therapy with pain still occurring with minimal provocation;
- IV-C - Pain requiring coronary care unit monitoring and parenteral medications and/or intra-aortic balloon counterpulsation.

Clinical definitions of unstable angina lack predictive value, and the search for a biochemical marker is underway. By convention, unstable angina has been differentiated from non-Q wave MI only retrospectively by cardiac enzyme assessment. Although this distinction may have therapeutic and prognostic implications, recent studies suggest that unstable angina and non-Q wave MI are parts of an injury continuum. Very preliminary work with cardiac troponin T and troponin I levels, for example, have shown these enzymes to be elevated in most cases of unstable angina where creatine kinase enzyme levels are within the normal range (6-9). An adverse outcome is associated with higher enzyme levels. This implies that myocardial injury may be present in most cases of unstable angina as well. Distinctions among unstable angina, non-Q wave MI and Q wave MI are further blurred by the fact that non-Q wave MI often includes extensive *transmural* injury in the circumflex artery distribution, a region in which the ECG lacks adequate sensitivity to transmural injury (10)

3.2 PATHOPHYSIOLOGY OF UNSTABLE ANGINA

The acute coronary syndrome of unstable angina occurs frequently and is a potentially life-threatening medical condition. This clinical presentation contrasts with stable chronic coronary disease. The intriguing interface between acute and chronic presentations of ischemic heart disease has been examined in previous works (11,12). Some patients with established chronic atherosclerotic disease can remain stable for years without suffering acute events such as MI or unstable angina; in others these acute events seem to occur precociously and unpredictably on very limited atherosclerosis (11,12).

The pathological substrate is an unstable atherosclerotic plaque (13-15) frequently severely narrowing a coronary artery, although the degree of narrowing may well have been previously insignificant (16,17). Such a plaque is often lipid rich and has fissured (13-15,18). Platelet aggregation, thrombus formation and enhanced vasoconstriction appear to be involved in the

pathogenesis of the unstable plaque (14,19). More recently, inflammatory processes involving activation of lymphocytes and monocyte macrophages have also been implicated (20-24).

The risk of acute coronary syndromes such as unstable angina recurring during the hospital stay is 5% to 15% and in the year that follows varies from 10% to over 30% (25,26). The pathophysiological basis for this unpredictable event is just as unclear as why an atherosclerotic plaque destabilizes in the first place. It is assumed that a strong stimulus or combination of stimuli locally and possibly systemically is involved. This may involve an inappropriate prothrombogenic tendency systemically (27,28) or locally (29) or enhanced persistent vasoconstriction at the 'culprit' plaque site, as has been suggested following MI (30) and as recently demonstrated in unstable angina (31). Residual thrombus may predispose to recurrent thrombosis (32,33). Increased shear rate over a significant residual stenosis may predispose to recurrent platelet-mediated occlusion (34,35).

3.3 TREADMILL TESTING AND HOLTER MONITORING IN UNSTABLE ANGINA

Because acute coronary syndromes are characterized by a dynamic process with plaque deformation, platelet aggregation and clotting, it is not surprising that provocative tests aimed at exploring the impact of obstructions on coronary flow dynamics are often unreliable. Thus, noninvasive testing, particularly the treadmill exercise test, often lacks adequate precision as a sole means of identifying patients with acute coronary syndromes who are in need of diagnostic angiography and subsequent revascularization at an early phase in their illness. In fact, treadmill testing in the acute phase of unstable angina is thought to be relatively contraindicated because it carries an increased risk of further plaque destabilization and arrhythmias. With stabilization and after a short period of convalescence, however, exercise testing can be undertaken safely and may be helpful in triaging patients (36-39). Where the diagnosis of angina is questionable, treadmill testing can be used at an early stage to increase a clinicianâs confidence in deferring in-hospital monitoring or early angiography.

The importance of episodes of silent ischemia detected with ambulatory ECG monitoring is well established (40,41). The relative frequency of silent versus symptomatic ischemic episodes is high and has independent predictive value for in-hospital and 30-day outcomes. Further,

treatments that reduce silent ischemic events also alter in-hospital prognosis (42). These spontaneous episodes of angina have also been shown to identify patients with a recent MI who are at risk for reinfarction (43-45).

3.4 MEDICAL THERAPY IN UNSTABLE ANGINA

There are potential advantages to a strategy of medical treatment rather than intervention. Left alone, the culprit lesion may undergo a remodelling process with endogenous fibrinolysis and fibrous organization leading to stabilization of the lesion and possibly a reduction in the severity of the residual stenosis (46,47). Even when percutaneous transluminal coronary angioplasty (PTCA) is performed, and if clinical circumstances permit, it has been shown that PTCA can be associated with a better immediate outcome after a period of medical treatment than when it is performed early after the onset of unstable angina (48). However, possible disadvantages of an initial medical strategy may be a lower coronary arterial reserve, more limiting angina, a greater risk of recurrence of acute coronary events, and a delayed return to work and full social activities.

Initial medical treatment strategies include acetylsalicylic acid (ASA), long-acting nitrates and risk factor modification, usually with short term in-hospital monitoring. In many circumstances beta-blockers, calcium antagonists and the intravenous use of heparin and/or nitroglycerine are very effective. Newer antiplatelet agents with more potent plaque-stabilizing actions are being tested in randomized trials and show great promise.

4.1 The 'crossover issue'

Although the randomized surgical trials conclude that an initial strategy of medical management is appropriate for all patients with unstable angina because of equivalent hospital infarction and mortality rates in surgical and medical groups (49-54), that strategy very frequently requires subsequent revision. In Tables 3.1, 3.2 and 3.3, the crossover rates from the medical group to the surgical group in the randomized trials and one nonrandomized trial are listed. These data were acquired in the 1970s and the observed crossover rates may be quite different if the trials were repeated today. Further, all studies quoted are American. Crossover practice elsewhere may be quite different.

The rates varied from 1% to 10.5% per month, average 2.5% per month. Where ECG changes were present with pain, this rate was three times higher than when ECG changes were not present (51). Further, the crossover rates increased with the extent of disease (53) and time following presentation.

Because patients who crossed over to surgery had a mortality rate similar to that of the medical patients who did not cross over, there appears to have been no obvious disadvantage to an initial medical strategy for patients who initially stabilized on medical therapy.

Patients with unstable angina and suitable anatomy and ventricular function should be referred to surgery early to preserve any survival advantage that may be present. Those who follow an initial medical strategy because they lack evidence for a mortality benefit with surgery should be considered for PTCA if they are appropriate candidates and there is inadequate symptom control (see Chapter 1).

In the angioplasty era, the appropriate crossover strategy from initial medical management to PTCA is not clear. In the TIMI IIIB (Thrombolysis In Myocardial Infarction) trial, 61% of the early invasive group and 49% of the early conservative group eventually received a form of revascularization within 42 days ($P<0.001$); an equal number in each group received bypass surgery (24%). From a resource perspective, twice as many in the early conservative group required rehospitalization (14.1% versus 7.8%, $P<0.001$) and length of hospital stay was three times longer (49). At this time, relative cost data on the two strategies are not available. Finally, there is recent evidence that 25% of ischemia-related lesions that 'stabilize' on medical therapy progress over eight months, usually to total occlusion (55). The consequences of this progression are unclear in asymptomatic individuals, but the chances of primary success are reduced and the restenosis rates are very much higher when angioplasty is required in a totally occluded artery.

3.5 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

Following the initial diagnosis of an acute coronary syndrome, the presence of spontaneous angina and a positive exercise test for ischemia are thought to be markers of increased risk. This increased risk is thought to justify an aggressive investigative and treatment approach

(56,57). Even when symptoms are under satisfactory control, this appears to be an acceptable practice as long as a culprit lesion that is amenable to PTCA is identified (58-60).

There are possible advantages of angioplasty as an early treatment strategy for the culprit lesion in unstable angina. They are, first, rapid symptom relief and patient stabilization with early hospital discharge, early return to work and need for fewer medications; second, stabilization of the patient allowing later functional assessment of the need to revascularize the patient more completely ; and third, converting, often with the assistance of stents and other devices, a threatening complex lesion into a benign insignificant one, with the hope of reducing the risk of sudden vessel closure in the process. Symptoms are usually improved immediately following PTCA for unstable angina, but there are serious short term safety issues with this approach that have not been characterized adequately. Further, it is not certain that angioplasty assures greater stability of the culprit lesion with less subsequent reinfarction and unstable angina, although there is some preliminary evidence that this may be the case. PTCA often is a very expensive alternative not only acutely, particularly where multiple devices are required, but in the longer term as well because of the possibility of restenosis.

Trials that have sought to define the optimal therapeutic approach after thrombolysed MI have established *that there is no advantage to systematic acute or early PTCA following MI and thrombolysis* compared with a 'conservative' strategy of PTCA only in case of spontaneous or provoked ischemia (61,62). This was also found in the recent TIMI IIIB study of unstable angina and non-Q wave MI (49). Because these trials did not require a clinical indication for intervention other than the presence of a recent MI or unstable angina, it is no surprise that, *there being no clinical need, there was no clinical benefit.*

Table 3.1

Medicine to surgery crossover rates in four randomized trials and one prospective nonrandomized trial

Study	Crossover rate (%)	Follow-up interval	Enrolment years	Sample size	Reference
Palo Alto VA	20	18 months	1970-77	228	99
Dallas	36	6 months	1974-76	27	100
Portland VA	42	4 months	1972-75	40	54
VA Study	45	8 years	1976-82	468	87
VA Study	34	2 years	1976-82	468	101
NCSG ö LAD involvement	37	4 years	1972-76	202	85
NCSG ö ST elevation	45	42 months	1972-76	79	102
NCSG ö all	36	30 months	1972-76	288	53

LAD Left anterior descending artery; NCSG National Cooperative Study Group; VA Veterans Administration. Data from reference 99

TABLE 3.2

Randomized surgery versus medicine trials in unstable angina

n	Follow-up	Outcomes				Comments	Reference
		Mortality	Relief of angina	MI prevention	Exercise tolerance		
Trial (years enrolled)/Inclusion criteria							
Bertolasi (1970-73)							
113	32 months	Mortality reduced from 46% to 11% with surgery in UA with ECG changes; no difference in mortality in progressive angina group				Small numbers; 32-month follow-up	103
5-year VA Cooperative (1976-82)							
468	5 years	Overall	Recurrence	No difference	Increased		104,105

		mortality similar; surgery improved survival in 3VD and impaired LV function	of angina similar; lower nitrate and propranolol use in surgical group		in surgical group up to 5 years		
8-year VA Cooperative (1976-82)/UA with versus without ECG changes							
468	8 years	Overall equivalent medical and surgical mortality; decreased mortality with surgery in low EF-ECG change group				Small numbers in surgical subgroup showing benefit	106
8-year VA Cooperative (1976-82)							
468	8 years	Mortality lower with medical therapy in 1- and 2VD with normal EF; surgery lowered mortality in 3VD and EF <50%	Similar			Low power with poor EF groups; did not stratify into proximal LAD disease	107
10-year VA Cooperative (1976-82)							
468	10 years	Equivalent medical and surgical overall 10-year mortality; reduction in mortality with surgery in low EF group less than that observed at 5 and 8 years				50% crossover to surgery, mostly type I UA ö no ECG changes	86
CASS/80% male, 14% left main							
		87% 5-year					108

		survival, which decreased in 3VD, no difference in mortality if delayed 3 months					
NHLBI (1972-76)/ECG changes with pain							
288	30 months	Hospital and 30-month mortality the same	Class III-IV AP more common in medical patients in all groups	Hospital MI rate same, regardless of number of vessels		36% crossover to surgery by 30 months; percentage crossover correlated with extent of disease	108
NHLBI (1972-76)/>70% LAD							
202	4 years	Hospital mortality the same, 4-year mortality similar	Class III-IV AP more common in medical patients	No difference over 4 years			110
NHLBI (1972-76)/27% of 288 with ST elevation during pain							
79	42 months	Hospital mortality the same		Hospital MI rate the same		45% crossover to surgery by 42 months	111
Selden (1972-75)/ST or T wave changes after 24 h bed rest							
40	4 months	Same but small study	Improved with surgery		Improved with surgery	VF + hypothermia for myocardial preservation (40 patients)	112
Pugh (1974-76)/LAD 1VD, 2VD or 3VD							
50	36 months	Survival at 1.5 years equal	Improved with surgery			Only 27 patients	113

1VD Single vessel disease; 2VD Double vessel disease; 3VD Triple vessel disease; AP Angina pectoris; CASS Coronary Artery Surgery Study; ECG Electrocardiogram; EF Ejection fraction; LAD Left anterior descending artery; LV Left ventricular; MI Myocardial infarction; NHLBI National Heart, Lung, and Blood Institute; UA Unstable angina; VA Veterans Administration; VF Ventricular fibrillation

The interventional approach has never been tested against medical therapy, however, where spontaneous or provoked ischemia continues and where both interventional and medical approaches are viable options. This is true after MI where thrombolysis has been accomplished and in unstable angina. Where symptoms persist and where there is objective evidence for ischemia, should PTCA be performed early or should it be reserved for cases where medical treatment fails to control symptoms adequately?

3.5.1 Acute complications

Use of PTCA in patients with unstable coronary artery disease syndromes carries a higher risk of acute complications (63-66). Major complication rates in patients with unstable acute coronary syndromes vary from 3% to 12%, compared with 1% to 4% in patients with stable angina (67-69).

The reasons for this high complication rate appear to be related to the underlying pathophysiology. It has been demonstrated that the presence of preexisting intraluminal thrombus at angiography constitutes a risk factor for acute complications during or shortly after PTCA (70,71). Experimental studies have also shown that endothelial denudation, platelet adhesion, mural thrombus and localized vasoconstriction at the site of dilation may all result from PTCA (72,73). Thus, if performed in a setting of an acute coronary syndrome, it seems conceivable that balloon dilation itself may cause further injury to the already ulcerated intima and intensify the ongoing thrombogenic process. In addition, other possible mechanisms that are not detectable with conventional coronary angiography may play a role. Postmortem studies of patients with unstable coronary syndromes have demonstrated that spontaneous embolization of platelet aggregates can cause microinfarcts in small intramyocardial arteries (74). Furthermore, in situ coronary thrombi may contain degranulating platelets that release vasoconstrictors such as thromboxane A2 and serotonin (75,76). The release of the former is partially blocked by ASA. The leukocytes contained in recent thrombi can also produce leukotrienes that constitute potent microvascular vasoconstrictors (77,78). For instance, Wilson et al (79) have described a syndrome of intense microvascular constriction after PTCA of acute thrombotic coronary lesions, which was attributed to the release of potent vasoconstrictors from intraluminal thrombus.

3.5.2 Long term complications (restenosis)

Several studies, but not all, have documented very high rates of restenosis when PTCA is performed in patients with unstable angina (80,81). The mechanisms of this increased predisposition to restenosis remain unclear, although a growing body of evidence suggests that the phenomenon of spontaneous episodes of plaque rupture in acute coronary syndromes has features in common with the iatrogenic injury in

Transfer interrupted! Something missing

latelet aggregation at the site of injury (either spontaneous or PTCA-induced) leads to the release of mitogenic substances. Furthermore, histological studies in specimens retrieved by directional coronary atherectomy have demonstrated a comparable degree of smooth muscle cell proliferation in restenotic lesions and in primary lesions of patients with unstable angina (83). It is thus plausible that increased rates of restenosis in unstable angina may be related to the additive (or synergistic) effect of mechanical stimulation on already proliferating smooth muscle cells. The duration of this interval before a stable plaque is formed is uncertain, leaving unanswered the question of how long one should try to delay intervention in the presence of ongoing or provoked ischemia.

3.6 CORONARY ARTERY BYPASS GRAFTING

3.7.1 Randomized trial data

The results of major surgical trials in unstable angina are summarized in Table 3.2. The trials were designed to compare medical with surgical treatment outcomes, and all were performed in the 1970s, raising the question of applicability to cardiology in the mid-1990s.

Clearly, both medical options and surgical techniques have improved in the interim. The surgical trials used saphenous veins as the only bypass conduit, and the technique of myocardial protection was ventricular fibrillation with moderate systemic hypothermia - primitive by today's standards. The addition of PTCA into the therapeutic armamentarium for

unstable syndromes did not occur until the early 1980s. PTCA has not been subjected to a randomized comparison with surgery in unstable angina.

All surgical trials had important exclusion criteria that may limit the generalizability of their results. These exclusions are summarized in Table 3.3.

Patients with left main disease and those with more severe left ventricular dysfunction were generally not randomized in most unstable angina trials. For this group the mortality advantage of surgery over medical therapy would likely have been much greater than that seen in randomized patients (84).

TABLE 3.3

Exclusion criteria in the unstable angina randomized surgery versus medicine trials

Exclusion criteria	Reference
Left main disease	53,85,87,100
Ejection fraction <0.30	53,85,87,100
Elderly	
>65 years old	54
>70 years old	53,87
Previous CABG	101
Myocardial infarction <3 months	53,99,101,114
Severe distal disease	53,100,115
Females	87
Inadequate veins	54
Comorbidity	53,54
Hemodynamic instability	114
IABP needed	100
Failed PTCA	114

CABG Coronary artery bypass graft; IABP Intra-aortic balloon pump; PTCA Percutaneous transluminal coronary angioplasty

Notwithstanding the possible limitations of exclusion criteria and data ageing, the following conclusions with respect to surgical treatment of patients with unstable angina have not been challenged.

- Patients with single and double vessel disease had a higher mortality with surgical than with medical therapy in randomized surgery versus medical therapy randomized trials.

- A mortality benefit of surgery over medical therapy is seen in patients with triple vessel disease, particularly in those with coexisting left ventricular dysfunction.
- In subgroups where medical and surgical infarction and mortality are equivalent, the relief of angina is not as long lasting or profound in the medical cohorts as it is in the surgery group (50,53,85);
- Where left ventricular function is normal, long term survival in medical and surgicalgroups is equivalent up to 10 years (86). However, if left ventricular ejection fraction is less than 50, a survival benefit is demonstrated with surgery. The magnitude of this benefit, however, declines by 10 years, perhaps due to attrition of the exclusively used vein grafts (50,51,86,87).
- Exercise tolerance was better in the surgical arm of one randomized trial (88).

3.6.2 Coronary artery bypass grafting candidacy

Surgery is effective therapy in improving survival over me

Transfer interrupted! Somsthing missing

the following circumstances:

- triple vessel disease, particularly in patients with an ejection fraction <0.50;
- patients with a left main lesion > 60%; and
- patients with associated hemodynamically significant valvular disease, including intermittent ischemic regurgitation.

In addition, coronary artery bypass grafting (CABG) is appropriate treatment for symptom control with failure of medical management. Patients with single and double vessel disease are usually referred for PTCA in the event of medical failure. However, CABG may be selected if PTCA has failed, the patient is not suitable for this approach or if the appropriately informed patient prefers surgery.

3.7 MANAGEMENT STRATEGY

Unstable angina results from a combination of fixed atherosclerotic obstruction and a dynamic component related to plaque deformation, coronary vasoconstriction and thrombus. Initial steps in the acute medical management of these patients are aggressive treatment with intravenous and/or oral nitrates, anticoagulation with heparin, ASA, and beta-blockade with or without calcium antagonists, as indicated. This early treatment strategy usually entails admission to the coronary care unit, although the efficacy of this site of monitoring has never been defined in an appropriate trial.

Cardiac catheterization is performed routinely when patients are admitted to the hospital who are candidates for a revascularization procedure and have one or more of the following high risk indicators:

- persistent or recurrent pain;
- ECG changes suggestive of ischemia, specifically ST depression where the clinical urgency is directly proportional to the degree of ST depression (89);
- prior revascularization (PTCA or CABG);
- prior MI;
- associated congestive heart failure or depressed left ventricular function (ejection fraction <0.50); or
- malignant ventricular arrhythmias.

If the acute symptoms settle and high risk indicators are not present, coronary angiography is not indicated unless symptoms recur or noninvasive testing indicates the presence of significant ischemia (36,39). If symptoms recur coronary angiography is performed.

Where significant left main disease or triple vessel disease with reduced left ventricular function is identified, bypass surgery is indicated unless there is significant comorbidity or the patient is otherwise not suitable (see Chapter 1). It is likely that better myocardial protection, more complete revascularization, improved graft patency and improved symptom-free survival can be expected with modern surgical techniques than with those used at the time of the randomized trials. With single and double vessel disease, the decision to revascularize by angioplasty or bypass surgery or to persist with further medical trials is a complex one. The decision must take multiple dimensions into consideration, including the patientâs functional status and quality of life; recreational and occupational expectations; assessment of target lesion and the amount of myocardium at risk; patient preference; available facilities; and the experience and skill of local angioplasty and surgical teams. The choice between angioplasty and surgery is discussed more fully in Chapter 1.

Based on current knowledge, we believe that percutaneous revascularization in unstable angina should be offered to patients with suitable anatomy refractory to optimal medical therapy and to those who, despite stabilization, have unacceptable symptoms. PTCA of only the culprit lesion should be considered, due to the higher rate of acute and long term complications compared with patients with stable angina (58,60).

Although surgery for left main disease and triple vessel disease with poor left ventricular function has an advantage over medical therapy in unstable angina, there are other circumstances where the safety and long term benefit of a culprit lesion angioplasty approach should be carefully weighed against a surgical approach. These include situations where the culprit lesion is not clear, where the culprit vessel is the source of important collaterals, where anatomy and noninvasive testing suggest a substantial amount of myocardium at risk, and where diffuse proximal disease and other anatomical features portend a poor long term angioplasty result.

Several studies are underway to evaluate new antiplatelet regimens in high risk PTCA (glycoprotein IIb/IIIa receptor blockers), as well as new strategies such as local drug delivery (90) that are being developed to reduce the restenosis rate. It is hoped that these new therapeutic modalities will decrease the rate of acute thrombotic complications and the long term limitations of PTCA in unstable angina.

3.8 REVASCULARIZATION FOR UNSTABLE ANGINA - THE FUTURE

In formulating future revascularization resource forecasts, the following points were considered.

With new understanding concerning the pathogenesis of acute coronary syndromes, it is likely that the near future will see widespread clinical use of new antithrombins and antiplatelet agents as well as agents that protect the plaque from the effects of the invading macrophage (91,92). Because the lesion before plaque rupture is frequently not hemodynamically significant, it is likely that fewer patients will require mechanical intervention, at least acutely. On the other hand, the glycoprotein IIb/IIIa receptor blockers have been shown to significantly reduce acute complications in PTCA of patients with unstable angina, perhaps with a reduction in restenosis as well (93,94). This ongoing research may reduce previously held concerns about the increased risk and higher restenosis rates of PTCA when performed in the presence of unstable angina.

The advent of stenting as an adjunct to PTCA has created a greater degree of success and safety with interventions in unstable patients (95-98). With improved techniques it is likely that reluctance to intervene on only the culprit lesion in unstable angina will diminish, encouraging more complete revascularization with better long term outcome. The current strategy is to do the culprit lesion followed by later PTCA of lesions necessary to achieve clinically complete revascularization.

With new techniques and treatment options, more patients will be referred for cardiac catheterization to determine whether they qualify for these approaches. This has occurred with PTCA, and the trend will continue with other developments. It is expected that surgery will enjoy a constant share of these new referrals, primarily those with triple vessel disease.

Steady growth in use of angioplasty for treating unstable angina is projected to the year 2010. The future demand for surgery in unstable angina is not clear and will depend largely on whether the clear short term stabilizing benefit of angioplasty is translated into adequate long

term results. The most reasonable projection for the year 2010 is that the surgical demand will parallel the angioplasty numbers, similar to the trend over the past decade. The actual amount of revascularization growth per 100,000 population is entirely speculative, but 20% is a reasonable guess.

3.9 RECOMMENDATIONS

3.9.1 In unstable angina, there is no indication for routine cardiac catheterization and intervention. An initial conservative strategy is appropriate although medicine-to-revascularization crossover rates are expected to be high with this approach.

Grade: A

Level: I

3.9.2 In unstable angina, cardiac catheterization is indicated by

- persistent or recurrent pain;
- ischemia ECG changes with pain;
- prior revascularization;
- prior MI;
- congestive heart failure or depressed left ventricular function; malignant arrhythmia; and
- positive noninvasive evidence for ischemia.

Grade: A

Levels: I to V

3.9.3 In unstable angina, surgery is acceptable therapy in the presence of

- significant left main disease;
- triple vessel disease with ejection fraction <50; or
- significant coexisting valvular disease.

Grade: A

Level: I

3.9.4 In unstable angina, both angioplasty and surgery are effective means for pain control. Although CABG is more effective than medical therapy, the relative efficacy of CABG and angioplasty is uncertain.

Grade: C

Levels: III, IV and V

3.9.5 In unstable angina, angioplasty is preferred in single vessel disease and double vessel disease where the proximal left anterior descending artery is not involved, when other approaches have failed to provide adequate symptom relief.

Grade: C

Levels: III, IV and V

REFERENCES

1. Braunwald E. Unstable angina: a classification. Circulation 1989;80:410-4.

2. Rizik DG, Healy S, Margulis A, et al. A new clinical classification for hospital prognosis of unstable angina pectoris. Am J Cardiol 1995;75:993-7.

3. Farhi J-I, Cohen M, Fuster V. The broad spectrum of unstable angina pectoris and its implications for future controlled trials. Am J Cardiol 1986;58:547-50.

4. Campeau L. Grading of angina pectoris. Circulation 1975;54:522-3.

5. Cox J, Naylor CD. The Canadian Cardiovascular Society grading scale for angina pectoris: is it time for refinements? Ann Intern Med 1992;117:677-83.

6. Hamm CW, Ravkilde J, Gerhardt W, et al. The prognostic value of serum troponin T in unstable angina [see comments]. N Engl J Med 1992;327:146-50.

7. Machler H, Metzler H, Sabin K, et al. Preoperative myocardial cell damage in patients with unstable angina undergoing coronary artery bypass graft surgery [see comments]. Anesthesiology 1994;81:1324-31.

8. Karim MA, Shinn M, Oskarsson H, Windle J, Deligonul U. Significance of cardiac troponin T release after percutaneous transluminal coronary angioplasty. Am J Cardiol 1995;76:521-5.

9. Stanton E, Jackowski G, Bonnell R, et al. Biochemical differentiation between different classes of unstable angina. Circulation 1994;90:I664. (Abst)

10. Huey BL, Beller GA, Kaiser DL, Gibson RS. A comprehensive analysis of myocardial infarction due to left circumflex artery occlusion: comparison with infarction due to right coronary artery and left anterior descending artery occlusion. J Am Coll Cardiol 1988;12:1156-66.

11. Bogaty P, Dagenais GR, Cantin B, Alain P, Rouleau JR. Prognosis in patients with a strongly positive exercise electrocardiogram. Am J Cardiol 1989;64:1284-8.

12. Bogaty P, Brecker SJ, White SE, et al. A comparison of coronary angiographic findings at acute and chronic first presentation of ischemic heart disease. Circulation 1993;87:1938-46.

13. Davies MJ, Thomas AC. Plaque fissuring: the cause of acute myocardial infarction, sudden ischemic death and crescendo angina. Br Heart J 1985;53:363-73.

14. Gorlin R, Fuster V, Ambrose JA. Anatomic-physiologic links between acute coronary syndromes. Circulation 1986;74:6-9.

15. Falk E. Morphologic features of unstable atherothrombotic plaques underlying acute coronary syndromes. Am J Cardiol 1989;63:114E-20E.

16. Little WC, Constantinescu M, Applegate RJ, et al. Can coronary angiography predict the site of a subsequent myocardial infarction in patients with mild-to-moderate coronary artery disease? Circulation 1988;78:1157-66.

17. Ambrose JA, Tannenbaum M, Alexopoulos D, et al. Angiographic progression of coronary artery disease and the development of myocardial infarction. J Am Coll Cardiol 1988;12:56-62.

18. Richardson RD, Davies MJ, Born GVR. Influence of plaque configuration and stress distribution on fissuring of coronary atherosclerotic plaques. Lancet 1989;ii:941-4.

19. Maseri A, Chierchia S, Daview G. Pathophysiology of coronary occlusion in acute infarction. Circulation 1986;73:233-9.

20. Berk BC, Weintraub WS, Alexander RW. Elevation of C-reactive protein in ãactiveä coronary artery disease. Am J Cardiol 1990;65:168-72.

21. Neri Serneri GG, Abbate R, Gori AM, et al. Transient intermittent lymphocyte activation is responsible for the instability of angina. Circulation 1992;86:790-7.

22. Mazzone A, De Servi S, Ricevuti G, et al. Increased expression of neutrophil and monocyte adhesion molecules in unstable coronary artery disease [see comments]. Circulation 1993;88:358-63.

23. van der Wal AC, Becker AE, van der Loos CM, Das PK. Site of intimal rupture or erosion of thrombosed coronary atherosclerotic plaques is characterized by an inflammatory process irrespective of the dominant plaque morphology. Circulation 1994;89:36-44.

24. Liuzzo G, Biasucci LL, Gallimore JR, et al. The prognostic value of C-reative protein and serum amyloid A protein in severe unstable angina. N Engl J Med 1994;331:417-24.

25. Théroux P, Lidn R. Unstable angina. Curr Probl Cardiol 1993;18:157-232.

26. Cairns JA, Singer J, Gent M, et al. One year mortality outcomes of all coronary and intensive care unit patients with acute myocardial infarction, unstable angina or other chest pain in Hamilton, Ontario, a city of 375,000 people. Can J Cardiol 1989;5:239-46.

27. Hamsten A, De Faire U, Walldius G, et al. Plasminogen activator inhibitor in plasma: risk factor for recurrent myocardial infarction. Lancet 1987;ii:3-9.

28. Trip MD, Cats VM, van Capelle FJL, Vreeken J. Platelet hyperreactivity and prognosis in survivors of myocardial infarction. N Engl J Med 1990;322:1549-54.

29. Lupu F, Bergonzelli GE, Heim DA, et al. Localization and production of plasminogen activator inhibitor-1 in human healthy and atherosclerotic arteries. Arterioscler Thromb 1993;13:1090-100.

30. Bertrand ME, Lablanche JM, Tilmant PY, et al. Frequency of provoked coronary arterial spasm in 1089 consecutive patients undergoing coronary arteriography. Circulation 1982;65:1299-306.

31. Bogaty P, Hackett D, Davies G, Maseri A. Vasoreactivity of the culprit lesion in unstable angina. Circulation 1994;90:5-11.

32. Badimon L, Lassila R, Badimon JJ, Vallabhajosula S, Chesebro JH, Fuster V. Residual thrombus is more thrombogenic than severely damaged vessel wall. Circulation 1988;78:119. (Abst)

33. Badimon L, Badimon JJ, Lassila R, Merino A, Chesebro JH, Fuster V. Rethrombosis on an evolving thrombus is mediated by thrombus- bound thrombin that is not inhibited by systemic heparin. Thromb Haemost 1991;65:65. (Abst)

34. Badimon L, Badimon JJ. Mechanisms of arterial thrombosis in nonparallel streamlines: platelet thrombi grow on the apex of stenotic severely injured vessel wall. J Clin Invest 1989;84:1134-44.

35. Lassila R, Badimon JJ, Valabhajosula S, Badimon L. Dynamic monitoring of platelet deposition on severely damaged vessel wall in flowing blood: effects of different stenosis on thrombus growth. Arteriosclerosis 1990;10:306-15.

36. Freeman MR, Chisholm RJ, Armstrong PW. Usefulness of exercise electrocardiography and thallium scintigraphy in unstable angina pectoris in predicting the extent and severity of coronary artery disease. Am J Cardiol 1988;62:1164-70.

37. Butman SM, Olson HG, Butman LK. Early exercise testing after stabilization of unstable angina: correlation with coronary angiographic findings and subsequent cardiac events. Am Heart J 1986;111:11-8.

38. Marmur JD, Freeman MR, Langer A, Arrmstrong PW. Prognosis in medically stabilized unstable angina: early Holter ST-segment monitoring compared with predischarge exercise thallium tomography. Ann Intern Med 1990;113:575-9.

39. Butman SM, Olson HG, Gardin JM, Piters KM, Hullett M, Butman LK. Submaximal exercise testing after stabilization of unstable angina pectoris. J Am Coll Cardiol 1984;4:667-73.

40. Langer A, Freeman MR, Armstrong PW. ST segment shift in unstable angina: pathophysiology and association with coronary anatomy and hospital outcome. J Am Coll Cardiol 1989;13:1495-502.

41. Gottlieb SO, Weisfeldt ML, Ouyang P, Mellits ED, Gerstenblith G. Silent ischemia as a marker for early unfavorable outcomes in patients with unstable angina. N Engl J Med 1986;314:1214-9.

42. Holdright D, Patel D, Cunningham D, et al. Comparison of the effect of heparin and aspirin versus aspirin alone on transient myocardial ischemia and in-hospital prognosis in patients with unstable angina. J Am Coll Cardiol 1994;24:39-45.

43. Bosch X, Theroux P, Waters DD, Pelletier GB, Roy D. Early postinfarction ischemia: clinical, angiographic, and prognostic significance. Circulation 1987;75:988-95.

44. Dwyer EM, McMaster P, Greenberg H, Multicenter Postinfarction Research Group. Nonfatal cardiac events and recurrent infarction in the year after acute myocardial infarction. J Am Coll Cardiol 1984;4:695-702.

45. Taylor GJ, Humphries JO, Mellits ED, et al. Predictors of clinical course, coronary anatomy and left ventricular function after recovery from acute myocardial infarction. Circulation 1980;62:960-70.

46. Topol EJ, Califf RM, Vandormael M, et al. A randomized trial of late reperfusion therapy for acute myocardial infarction. Circulation 1992;85:2090-9.

47. Topol EJ, Califf RM, George BS, et al. A randomized trial of immediate versus delayed elective angioplasty after intravenous tissue plasminogen activator in acute myocardial infarction. N Engl J Med 1987;317:581-8.

48. Myler RK, Shaw RE, Stertzer SH, et al. Unstable angina and coronary angioplasty. Circulation 1990;82:88-95.

49. Effects of tissue plasminogen activator and a comparison of early invasive and conservative strategies in unstable angina and non-Q-wave myocardial infarction. Results of the TIMI IIIB Trial. Thrombolysis in Myocardial Ischemia. Circulation 1994;89:1545-56.

50. Roos LL, Sharp SM. Innovation, centralization and growth: coronary artery bypass graft surgery in Manitoba. Med Care 1989;27:441-52.

51. Morin JE, Symes JF, Guerraty AJ, Poirier NL, Sampalis J. Coronary artery bypass profile in Canada and the United States. Can J Cardiol 1990;6:319-22.

52. Carol RJ, Horn SD, Soderfeldt B, James BC, Malmberg L. International comparison of waiting times for selected cardiovascular procedures. J Am Coll Cardiol 1995;25:557-63.

53. Unstable angina pectoris: National Cooperative Study Group to compare surgical and medical therapy. II: In-hospital experience and initial follow-up results in patients with one, two and three vessel disease. Am J Cardiol 1978;42:839-48.

54. Cox JL, Petrie JF, Pollak PT, Johnstone DE. Managed delay for coronary artery bypass graft surgery. Experience at one Canadian centre. 1996;27:1365-73.

55. Chen L, Chester MR, Redwood S, Huang J, Leatham E, Kaski JC. Angiographic stenosis progression and coronary events in patients with 'stabilized' unstable angina. Circulation 1995;91:2319-24.

56. Epstein S, Palmeri ST, Patterson RE. Evaluation of patients after acute myocardial infarction: indications for cardiac catheterization and surgical intervention. N Engl J Med 1982;307:1487-92.

57. Sami M, Kraemer H, DeBusk RF. The prognostic significance of serial exercise testing after myocardial infarction. Circulation 1979;60:1238-46.

58. Wohlgelernter D, Cleman M, Highman HA, Zaret BL. Percutaneous transluminal coronary angioplasty of the 'culprit lesion' for management of unstable angina pectoris in patients with multivessel coronary artery disease. Am J Cardiol 1986;58:460-4.

59. Breisblatt WM, Barnes JV, Weiland F, Spaccavento LJ. Incomplete revascularization in multivessel percutaneous transluminal coronary angioplasty: the role for stress thallium-201 imaging. J Am Coll Cardiol 1988;11:1183-90.

60. de Feyter PJ, Serruys PW, Arnold A, et al. Coronary angioplasty of the unstable angina related vessel in patients with multivessel disease. Eur Heart J 1986;7:460-7.

61. Williams DO, Braunwald E, Knatterud G, et al. One-year results of the Thrombolysis in Myocardial Infarction Investigation (TIMI) phase II trial. Circulation 1992;85:533-42.

62. Simoons ML, Arnold AE, Betriu A, et al. Thrombolysis with tissue plasminogen activator in acute myocardial infarction: no additional benefit from immediate percutaneous coronary angioplasty. Lancet 1988;i:197-203.

63. de Feyter PJ, Serruys PW, van den Brand M, et al. Emergency coronary angioplasty in refractory unstable angina. N Engl J Med 1985;313:342-6.

64. de Feyter PJ. Coronary angioplasty for unstable angina. Am Heart J 1989;118:860-8.

65. de Feyter PJ, Suryapranata H, Serruys PW, et al. Coronary angioplasty for unstable angina: immediate and late results in 200 consecutive patients with identification of risk factors for unfavorable, early and late outcome. J Am Coll Cardiol 1988;12:324-33.

66. Plante S, Laarman GJ, de Feyter PJ, et al. Acute complications of percutaneous transluminal coronary angioplasty for total occlusion. Am Heart J 1991;121:417-26.

67. Black AJ, Brown CS, Feres F, Roubin GS, Douglas JS. Coronary angioplasty and the spectrum of unstable angina pectoris: what determines increased risk? Circulation 1988;78:8. (Abst)

68. Detre K, Holubkow R, Kelsey S, Co-Investigators of the NHLBI PTCA Registry. Percutaneous transluminal coronary angioplasty in 1985-1986 and 1977-1981. The National Heart, Lung, and Blood Institute Registry. N Engl J Med 1988;318:265-70.

69. Block PC. Percutaneous transluminal coronary angioplasty: role in the treatment of coronary artery disease. Circulation 1985;72:161-5.

70. Mabin TA, Holmes DR, Smith HC, et al. Intracoronary thrombus: role in coronary occlusion complicating percutaneous transluminal coronary angioplasty. J Am Coll Cardiol 1985;5:198-202.

71. Sugrue D, Holmes DR, Smith HC, et al. Coronary artery thrombus as a risk factor for acute vessel occlusion during percutaneous transluminal coronary angioplasty: improving results. Br Heart J 1986;56:62-6.

72. Pasternak RC, Baughman KL, Fallon JT, Block PC. Scanning electron microscopy after coronary transluminal angioplasty of normal coronary arteries. Am J Cardiol 1980;45:591-8.

73. Lam JYT, Chesebro JH, Steele PM, Badimon L, Fuster V. Is vasospasm related to platelet deposition? Relationship in a porcine preparation of arterial injury in vivo. Circulation 1987;73:243-8.

74. Falk E. Unstable angina with fatal outcome: dynamic coronary thrombosis leading to infarction and/or sudden death. Autopsy evidence of recurrent mural thrombosis with peripheral embolization culminating in total vascular occlusion. Circulation 1985;71:699-708.

75. Chapman I. Morphogenesis of occluding coronary artery thrombosis. Arch Pathol 1965;80:256-61.

76. Morooka S, Kobayashi M, Takahashi T, Takashima Y, Sakamoto M, Shimamoto T. Experimental ischaemic heart disease ö effects of synthetic thromboxane A2.. Exp Mol Pathol 1979;30:449-57.

77. Michelassi F, Landa L, Hill RD, et al. Leukotriene D4: a potent coronary artery vasoconstrictor associated with impaired ventricular contraction. Science 1982;217:841-3.

78. Letts LG, Newman DL, Greewald SE, Piper PJ. Effects of intracoronary administration of leukotriene D4 in the anestetized dog. Prostaglandins 1983;26:563-4.

79. Wilson RF, Laxson DD, Lesser JR, White CW. Intense microvascular constriction after angioplasty of acute thrombotic coronary arterial lesions. Lancet 1989;i:807-11.

80. Leimgruber PP, Roubin GS, Hollman J, et al. Restenosis after successful coronary angioplasty in patients with single-vessel disease. Circulation 1986;73:710-7.

81. de Groote P, Bauters C, McFadden EP, Lablanche JM, Leroy F, Bertrand ME. Local lesion-related factors and restenosis after coronary angioplasty. Evidence from a quantitative angiographic study in patients with unstable angina undergoing double-vessel angioplasty. Circulation 1995;91:968-72.

82. Fuster V, Badimon L, Badimon JJ, Chesebro JH. The pathogenesis of coronary artery disease and the acute coronary syndromes (part I). N Engl J Med 1992;326:242-50.

83. Flugelman MY, Virmani R, Correa R, et al. Smooth muscle cell abundance and fibroblast growth factors of patients with nonfatal unstable angina: a clue to the mechanism of transformation from the stable to the unstable clinical state. Circulation 1993;88:2493-500.

84. Takaro T, Peduzzi P, Detre KM, et al. Survival in subgroups of patients with left main coronary artery disease. Veterans Administration cooperative study of surgery for coronary arterial occlusive disease. Circulation 1982;66:14-22.

85. Christakis G, Ivanov J, Weisel RD, et al. The changing pattern of coronary artery bypass surgery. Circulation 1989;80:I151-61.

86. Scott SM, Deupree RH, Sharma GV, Luchi RJ. VA study of unstable angina. 10-year results show duration of surgical advantage for patients with impaired ejection fraction. Circulation 1994;90:II120-3.

87. Naylor CD. A different view of queues in Ontario. Health Aff (Millwood) 1991;10:110-28.

88. Mark DB, Nelson CL, Califf RM, et al. Continuing evolution of therapy for coronary artery disease: initial results from the era of coronary angioplasty. Circulation 1994;89:2015-25.

89. Lee HS, Cross SJ, Rawles JM, Jennings KP. Patients with suspected myocardial infarction who present with ST depression. Lancet 1993;342:1204-7.

90. Plante S, Dupuis G, Mongeau CJ, Durand P. Porous balloon catheters for local delivery: assessment of vascular damage in a rabbit iliac angioplasty model. J Am Coll Cardiol 1994;24:820-4.

91. Theroux P, White H, David D, et al. A heparin-controlled study of MK-383 in unstable angina. Circulation 1994;90:I231. (Abst)

92. Theroux P, Kouz S, Knudtson M, et al. A randomized double-blind controlled trial with the non-peptidic platelet GP IIb/IIIa antagonist RO 44-9883 in unstable angina. Circulation 1994;90:I232. (Abst)

93. Use of a monoclonal antibody directed against the platelet glycoprotein IIb/IIIa receptor in high-risk coronary angioplasty. The EPIC Investigation. N Engl J Med 1994;330:956-61.

94. Topol EJ, Califf RM, Weisman HF, et al. Randomised trial of coronary intervention with antibody against platelet IIb/IIIa Integrin for reduction of clinical restenosis: results at six months. Lancet 1994;343:881-6.

95. Serruys PW, de Jaegere P, Kiemeneij F, et al. A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331:489-95.

96. Colombo A, Hall P, Nakamura S. Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. Circulation 1995;91:1676-88.

97. Baim DS, Kent KM, King SB III, et al. Evaluating new devices. Acute (in-hospital) results from the New Approaches to Coronary Intervention Registry. Circulation 1994;89:471-81.

98. Schšmig A, Dastrati A, Mudra H, et al. Four-year experience with Palmaz-Schatz stenting in coronary angioplasty complicated by dissection with threatened or present vessel closure. Circulation 1995;90:2716-24.

99. Spence PA, Gray LA Jr. New conduits for coronary artery bypass: great promise for improved outcome from coronary artery surgery. J Ky Med Assoc 1994;92:52-8.

100. Williams TE Jr, Fanning WJ, Leila L, et al. Can we afford to do cardiac operations in 1996? A risk-reward curve for cardiac surgery. Ann Thorac Surg 1994;58:815-21.

101. Luchi RJ, Scott SM, Deupree RH. Comparison of medical and surgical treatment for unstable angina pectoris: results of a Veterans Administration Cooperative Study. N Engl J Med 1987;316:977-84.

102. Higginson LAJ, Cairns JA, Keon WJ, Smith ER. Rates of cardiac catheterization, coronary angioplasty and open-heart surgery in adults in Canada. Can Med Assoc J 1992;146:921-5.

103. Bertolasi CA, Tronge JE, Riccitelli MA, Villamayor RM, Zuffardi E. Natural history of unstable angina with medical or surgical therapy. Chest 1976;70:596-605.

104. Booth DC, Deupree RH, Hultgren HN, DeMaria AN, Scott SM, Luchi RJ. Quality of life after bypass surgery for unstable angina. 5-year follow-up results of a Veterans Affairs Cooperative Study. Circulation 1991;83:87-95.

105. Parisi AF, Khuri S, Deupree RH, Sharma GV, Scott SM, Luchi RJ. Medical compared with surgical management of unstable angina. 5-year mortality and morbidity in the Veterans Administration Study. Circulation 1989;80:1176-89.

106. Sharma GVRK, Deupree RH, Khuri SF, Parisi AF, Luchi RJ, Scott SM. Coronary bypass surgery improves survival in high risk unstable angina. Results of a Veterans Administration Cooperative Study with an 8-year follow-up. Circulation 1991;84:III260-7.

107. Sharma GV, Deupree RH, Luchi RJ, Scott SM. Identification of unstable angina patients who have favorable outcome with medical or surgical therapy (eight-year follow-up of the Veterans Administration Cooperative Study). Am J Cardiol 1994;74:454-8.

108. McCormick JR, Schick EC Jr, McCabe CH, Kronmal RA, Ryan TJ. Determinants of operative mortality and long-term survival in patients with unstable angina. The CASS experience. J Thorac Cardiovasc Surg 1985;89:683-8.

109. Unstable angina pectoris: National Cooperative Study Group to Compare Surgical and Medical Therapy. Am J Cardiol 1978;42:839-48.

110. Unstable angina pectoris: National Cooperative Study Group to Compare Medical and Surgical Therapy. IV. Results in patients with left descending coronary artery disease. Am J Cardiol 1981;48:517-24.

111. Unstable angina pectoris: National Cooperative Study Group to Compare Surgical and Medical Therapy. III. Results in patients with S-T segment elevation during pain. Am J Cardiol 1980:45:819-24.

112. Selden R, Neill WA, Ritzmann LW, Okies JE, Anderson RP. Medical versus surgical therapy for acute coronary insufficiency. A randomized study. N Engl J Med 1975;293:1329-33.

113. Pugh B, Platt MR, Mills LJ, et al. Unstable angina pectoris: a randomized study of patients treated medically and surgically. Am J Cardiol 1978;41:1291-8.

114. Cameron AA, Green GE, Brogno DA, Thornton J. Internal thoracic artery grafts: 20-year clinical follow-up. J Am Coll Cardiol 1995;25:188-92.

115. Peters S, Chagani K, Paddon P, et al. Coronary artery bypass surgery in Canada. Health Rep 1990;2:9-26.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 4: Myocardial Infarction

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There is now unequivocal evidence of benefit with the use of intravenous thrombolytic therapy for acute myocardial infarction (AMI). This chapter addresses the role of percutaneous transluminal coronary angioplasty (PTCA) for the treatment of AMI. The potential of this technique to achieve early and complete coronary reperfusion and less recurrent ischemia is reviewed.

4.1 DEFINITIONS

In the literature and in practice confusion has been generated by the inconsistency of terminology used to define the various strategies involving PTCA in the treatment of AMI. For the purpose of this discussion, the definitions listed below are used.

Primary coronary angioplasty, also known as direct or infarct angioplasty, is defined as the dilation of an infarct-related artery during the acute phase of a myocardial infarction without prior administration of thrombolytic therapy.

Immediate adjunctive coronary angioplasty is defined as the routine dilation of an infarct-related artery as soon as possible after the administration of a thrombolytic agent, regardless of whether thrombolysis was successful.

Rescue coronary angioplasty is the dilation of an infarct-related artery immediately after failure of thrombolysis in an attempt to salvage myocardium by opening a persistently occluded artery.

Deferred adjunctive coronary angioplasty is the routine prophylactic dilation of an infarct-related artery within the first week after AMI to prevent recurrent ischemia.

4.2 INITIAL REPORTS

The first reported use of angioplasty for the treatment of AMI was in 1982, by Meyer and associates (1). Twenty-one patients were reported to have undergone angioplasty after *intracoronary* streptokinase. Of these cases, 81% were successful and, of note, this report included the first description of primary PTCA in a patient in cardiogenic shock.

Several studies followed of various centres' experience with PTCA in the setting of AMI including reports from the Mid America Heart Institute (2) and the Mayo Clinic (3).

These initial reports were difficult to interpret: they described a mixture of strategies, including primary and adjunctive PTCA, with various intravenous and intracoronary thrombolytic agents, and most were nonrandomized descriptive reports. However, *all* centres reported a high procedural success rate.

After these early reports describing the safety of PTCA in AMI, several large series of consecutive patients were published and are summarized in Table 4.1.

The largest series by OâKeefe and colleagues (4) was first reported in 1989, from the Mid America Heart Institute. In 1993, O'Keefe et al (5) published an updated report of 1000 registry patients from a 13-year period. The initial PTCA success rate was 94%, the need for in-hospital coronary artery bypass grafting was 1.4%, and the overall mortality during hospitalization was 7.8%. These results are comparable with those seen in the other studies from smaller centres.

It is important to note that all series except that of O'Neill et al (6) included patients who would have been ineligible for intravenous thrombolytic therapy and those in cardiogenic shock. This is reflected in the higher mortality rates seen in these studies compared with that of O'Neill et al.

Long term follow-up of patients from earlier studies shows that survival rates are maintained up to five years postprocedure. Restenosis rates are difficult to estimate; serial routine angiographic follow-up is not available. However, symptomatic restenosis rates range from 15% to 35% (7).

4.3 RANDOMIZED TRIALS OF PRIMARY CORONARY ANGIOPLASTY

O'Neill et al (8) reported the first randomized trial of primary coronary angioplasty in 1986, comparing *intracoronary* streptokinase with the strategy of primary angioplasty. The end-points were the infarct-related artery patency and the change in left ventricular ejection fraction as measured by radionuclear angiogram. This study showed improved left ventricular function in the PTCA group. However, its small number and the comparison with intracoronary thrombolysis, which is an uncommon strategy in the 1990s, limit the study.

In 1993 Ribeiro et al (9) published a randomized trial of 100 patients from Brazil treated with either primary angioplasty or intravenous streptokinase. The primary end-point was infarct-related artery patency at 48 h, and the outcome was similar with both treatment arms. Unfortunately, 48 h patency does not necessarily represent salvage of myocardium. There was no difference between the groups in 48 h patency of the infarct-related artery or in left ventricular function.

In 1993, researchers at the Mayo Clinic reported 108 patients randomized to either intravenous recombinant tissue-type plasminogen activator (t-PA) or primary angioplasty (10). The primary end-point was the amount of myocardium salvaged as measured by the difference in the size of the perfusion defect seen on sesta-MIBI scan. No differences were found between the strategies in the primary end-point of myocardial salvage as measured by MIBI scan, left ventricular ejection fraction, mortality or cost.

The Netherlands trial of intravenous streptokinase versus primary angioplasty initially reported 142 patients showing improved infarct-related artery patency and left ventricular ejection fraction with primary PTCA (11). They then went on to complete a randomized study to assess clinical benefit. The end-points were left ventricular ejection fraction, in-hospital mortality, recurrent ischemia and reinfarction. The final study reported 301 cases showing a significant improvement in left ventricular ejection fraction, recurrent ischemia, mortality and reinfarction with primary PTCA compared with intravenous streptokinase.

In 1993, the PAMI (Primary Angioplasty in Myocardial Infarction) trial reported 395 patients randomized to primary angioplasty or intravenous t-PA within 12 h of symptom onset (12). The primary end-point of mortality and/or recurrent ischemia was significantly better in the primary PTCA group (5.1% versus 12%, P=0.02). There was no significant difference in mortality unless one looked at the high risk group that showed a mortality of 2% in the primary angioplasty group versus 10.4% with t-PA. The left ventricular ejection fractions of the two groups were not different at discharge. Although diltiazem, now known to be harmful when used routinely in this setting, was given in the PAMI trial, both treatment arms received this drug. There was an unusually high (3.5%) incidence of intracranial bleeding in the thrombolysis group.

TABLE 4.1

Direct percutaneous transluminal coronary angioplasty: Nonrandomized studies

Study	Reference	Number of patients	Success (%)	CABG (%)	Death (%)	Reocclusion (%)
O'Keefe et al	5	1000	94	1.4	7.8	13.0
Brodie et al	7	202	91	4.4	8.9	NR
Rothbaum et al	50	151	87	1.5	9.0	9.0
O'Neill et al	8	271	98	5.0	4.0	NR

CABG Coronary artery bypass graft; NR Not recorded

TABLE 4.2

Randomized primary PTCA trials

Study	Reference	Number of patients	Agent	End-points	Result	Limits
O'Neill (1986)	8	56	IC Stk	IRA patency LVEF	PTCA PTCA	IC Stk small N
Ribeiro (1993)	9	100	IV Stk	48 h patency LVEF	equal equal	48 h end-point
Mayo Clinic (1993)	10	108	IV t-PA	Myocardial salvage (MIBI)	equal	Including ST-dependent use of MIBI
Netherlands (1994)	11	301	IV Stk	LVEF Recurrent ischemia Mortality Reinfarction IRA patency	Stk = 45±12 PTCA = 51±11 Stk = 14/72 PTCA = 4/70 Stk = 4/72 PTCA = 0/70 Stk = 9/72 PTCA = 0/70 Stk = 68% PTCA = 91%	Included Killip 3+4
PAMI (1993)	12	395	IV t-PA weight adjusted	Death and/or MI at 6 months mortality LVEF	t-PA = 16.8% PTCA = 8.5% t-PA = 6.5% PTCA = 2.6% t-PA = PTCA (both 53±13%)	Diltiazem High stroke With t-PA

IC Intracoronary; IRA Infarct-related artery; IV Intravenous; LVEF Left ventricular ejection fraction; MI Myocardial infarction; N Number of study participants; PAMI Primary Angioplasty in Myocardial Infarction; PTCA Percutaneous transluminal coronary angioplasty; Stk Streptokinase; t-PA Tissue-type plasminogen activator

4.4 SUMMARY OF RANDOMIZED PRIMARY ANGIOPLASTY TRIALS

The randomized trials of primary PTCA versus thrombolysis are summarized in Table 4.2 (13).

4.5 META-ANALYSIS OF THE RANDOMIZED TRIALS OF PRIMARY PTCA

In January 1995, Michels and Yusef (14) published a meta-analysis of the randomized trials of primary PTCA versus thrombolysis. The five trials listed in Table 4.2, as well as data from abstracts authored by DeWood et al (15) and Elizaga et al (16) were analyzed. No important statistical heterogeneity was observed among the seven trials. The primary end-point of the meta-analysis was six-week mortality. Other end-points were mortality at one year and nonfatal myocardial infarction at six weeks and at one year.

Data on in-hospital or six-week mortality were available for all seven trials. However, long term data were not available on enough patients in the seven trials to allow analysis beyond six weeks. The results of events at six weeks and one year are summarized in Table 4.3. Primary PTCA led to a reduction in mortality with an odds ratio of 0.56 and 95% CI 0.33 to 0.94. Combining deaths and nonfatal myocardial infarction, there was also a reduction in risk with an odds ratio of 0.53 and 95% CI of 0.35 to 0.80.

This meta-analysis suggests lower mortality and reinfarction rates with primary PTCA than with thrombolysis. However, interpretation of these results must be cautious. It is imperative that physicians reviewing these data be aware that these studies were done in specialized laboratories with a large experience in the performance of primary PTCA. It is possible that smaller, less experienced centres would not be able to duplicate these results. It is also important to review the time to treatment issue in these data. Patients reported in these trials had rapid access to interventions not available in centres that do not have a catheterization laboratory available 24 h each day. Indeed scheduling considerations may render assured access impossible even in some Canadian centres with these resources.

It should also be noted that only two of the trials showed an improvement in left ventricular function with PTCA over thrombolysis, and long term follow-up remains to be assessed in most.

Although this consensus feels that surgical backup rapidly available is important to direct PTCA, the feasibility of direct PTCA with and without surgery backup has been studied (17).

4.6 COST EFFECTIVENESS OF PRIMARY PTCA

The Mayo Clinic published a prospective randomized substudy on cost effectiveness of the primary PTCA approach versus thrombolysis with t-PA (18). Direct costs including all hospital and professional charges for initial and subsequent hospitalizations and treatment up to 12 months were recorded. Indirect costs were calculated by a formula that used days of hospitalization, time until return to work, change in work status, change in personal income, level of physical activity, quality of life questionnaire and number of additional procedures required.

The results of the cost comparison showed *no difference* in the direct costs of initial treatment with intravenous thrombolysis with t-PA or primary angioplasty. The indirect cost comparison showed a trend towards lower costs in the primary PTCA group. The overall mean monetary investment to salvage 1% of the left ventricle was absolutely identical in the two groups. Reanalysis substituting the cost of strepto- kinase for the cost of t-PA continued to show no statistical difference (18).

Himbert and colleagues reported similar results at the World Congress of Cardiology in 1994.

The Mayo Clinic and Himbert data are unlikely to be applicable to the Canadian health care system, where the costs of hospital and physician services differ from those in the United States, and where many hospitals do not have direct access to 24 h availability of interventional catheterization services. Thus, estimation of cost effectiveness of primary PTCA in the Canadian system would have to include several factors. These factors include the cost of transferring patients to centres with the necessary equipment and personnel, as well as the cost of delaying other patients on the waiting list in order to accommodate the emergency.

TABLE 4.3

Combined event data from primary percutaneous transluminal coronary angioplasty randomized trials

		Death before 6 weeks		Death or infarction before 6 weeks	
Trial	**References**	**Invasive**	**Noninvasive**	**Invasive**	**Noninvasive**
OâNeill	8	2/29*	1/27*	3/29*	2/27*
DeWood	15	3/46	2/44	3/46	2/44
PAMI	12	5/195*	13/200*	10/195*	24/200*
Netherlands	11	3/152*	11/149*	5/152*	23/149*
Mayo	10	2/47	2/56*	2/47*°	2/56*°
Ribeiro	9	3/50	1/50	5/50	2/50
Elizaga	16	3/52	7/48	7/52	8/48
Total		21/571 (3.7%)	37/574 (6.4%)	35/571 (6.1%)	63/574 (11.0%)

**At hospital discharge; °Only mortality data. PAMI Primary Angioplasty in Myocardial Infarction*

The most important variable, however, continues to be time to reperfusion. Therefore, primary PTCA cannot be considered to be superior to thrombolysis when a significant delay to the intervention is anticipated. The optimal time window for direct angioplasty is likely 1 h, although the time period could be extended in some circumstances.

When chosen, primary PTCA leads to less recurrent ischemia and a shorter hospital stay than when intravenous thrombolysis is selected. The effects on left ventricular function are variable. The cost effectiveness of primary PTCA has not been assessed in the Canadian health care system.

4.7 PRIMARY ANGIOPALSTY IN SELECTED PATIENT GROUPS

.7.1 Cardiogenic shock

Presentation of AMI complicated by cardiogenic shock is known to carry an extremely high mortality rate, with survival of only 10% to 20%.

Data from the Mayo Clinic on 45 patients with cardiogenic shock revealed a hospital survival rate of 71% in patients for whom primary coronary angioplasty was successful. In contrast, the survival rate was only 29% in those who failed to achieve reperfusion with PTCA (19).

A second multicentre series of patients with cardiogenic shock was published in 1991 by Lee and colleagues (20). They reported the outcome of primary angioplasty in 69 patients, with a procedural success rate of 71% and a survival rate of 69% in those for whom primary PTCA was successful. Although these studies are retrospective and nonrandomized, the survival rates for those who achieve successful reperfusion by PTCA are a marked improvement over expected rates based on historical controls (21-24). Cardiogenic shock registry data imply that patient selection plays a very important role in the favourable numbers quoted above, and the independent impact of PTCA on outcome remains unclear. With careful patient selection, excellent results have been reported with bypass surgery as well.

It is important to note that guidelines for primary PTCA for the treatment of AMI complicated by cardiogenic shock should follow the same principles as reperfusion by pharmacological means. That is to say that the earlier reperfusion is achieved, the more likely it is to salvage a significant amount of myocardium. Therefore, primary PTCA is likely to be of most benefit in the first few hours after the onset of symptoms. The risks are likely to outweigh the benefits after 6 to 12 h after the onset of symptoms. An ongoing randomized trial is assessing the role of primary PTCA for the treatment of cardiogenic shock, which may help to clarify these issues. It is clear, however, that the use of thrombolytic agents has consistently failed to show a survival advantage over the discouraging outcome data from the prethrombolytic era.

4.7.2 Thrombolytic ineligible patients

Thrombolytic therapy is withheld from patients with a high risk of bleeding or other contraindications. Therefore, primary coronary angioplasty is the treatment of choice in this group as long as they do not have exclusions for the administration of heparin. Registry reports and descriptive studies of primary PTCA in patients who have contraindications to thrombolysis have shown that high procedural success rates and low mortality rates can be achieved (25,26).

4.7.3 Elderly patients

Elderly patients with AMI are known to have a high risk of mortality and morbidity. Although thrombolysis has been shown to be associated with an increased risk of complications in this group, this increased risk is well balanced by a significant benefit with thrombolytic therapy. To date, reports on primary PTCA in the elderly have shown variable results, and further study is needed.

4.7.4 Nondiagnostic electrocardiogram

Urgent diagnostic catheterization is a reasonable option for patients presenting with symptoms of AMI and a nondiagnostic electrocardiogram, and where attempts to stabilize the patient medically have failed. If a culprit lesion can be identified with suitable anatomy, primary PTCA

can then be performed if needed personnel and resources are available. In other words, the patient should be treated as having unstable angina (see Chapter 3).

A possible exception to this rule is the patient who presents with typical ischemic pain with greater than 2 mm ST depression in the right precordial leads. The inferior and lateral leads should be examined very carefully for evidence compatible with a circumflex distribution infarction. If evidence for a posterolateral infarction is confirmed or expected, a more aggressive approach (thrombolytic therapy or early movement towards direct angioplasty) may be indicated.

4.8 IMMEDIATE ADJUNCTIVE PTCA

The rationale behind immediate adjunctive PTCA (routine dilation of an infarct-related artery early after administration of thrombolysis) is an attempt to resolve the residual stenosis after successful thrombolysis. Three major randomized trials have looked at immediate adjunctive PTCA.

The TAMI I (Thrombolysis and Angioplasty in Myocardial Infarction) trial randomized 386 patients after *angiographically proven* successful intravenous thrombolysis to either immediate adjunctive PTCA or delayed adjunctive PTCA at seven to 10 days postmyocardial infarction (27).

The TIMI IIA (Thrombolysis in Myocardial Infarction) substudy randomized patients after intravenous thrombolysis to one of three strategies (28-31):

1. immediate adjunctive PTCA (less than 2 h);
2. delayed adjunctive PTCA (18 to 48 h); or
3. conservative therapy.

The European Cooperative Study Group similarly randomized patients to either immediate adjunctive PTCA or conservative therapy after administration of intravenous thrombolysis (32,33).

The results of all three major trials of immediate adjunctive angioplasty showed increased mortality in the immediate adjunctive PTCA group compared with the more conservative group. This reached statistical significance in the European Cooperative Study. The need for emergency bypass and the frequency of bleeding was increased in the immediate adjunctive PTCA group, and there was no difference in the left ventricular ejection fraction between groups.

4.9 RESCUE CORONARY ANGIOPLASTY

Intravenous thrombolysis is known to achieve TIMI grade III reperfusion in only 55% to 90% of cases. Failure of intravenous thrombolysis is known to be associated with increased mortality and decreased left ventricular ejection fraction. The strategy of rescue angioplasty is to open the occluded infarct-related artery after *failure* of thrombolysis, in a timely fashion in order to salvage myocardium and potentially benefit mortality (34).

The first randomized prospective report of rescue PTCA was from Belenkie et al (35). This and other nonrandomized descriptive reports led to the design of the Rescue trial.

The Randomized Evaluation of Salvage angioplasty with Combined Utilization of Endpoints (RESCUE) was a randomized study of rescue PTCA versus medical therapy after *failed* intravenous thrombolysis. One hundred and fifty patients were enrolled at 20 centres with *anterior first myocardial infarctions.* A requirement for enrolment was to have a persistently occluded infarct-related artery (TIMI grade 0 or 1 flow) at catheterization done 1.5 to 8 h postinfarction. Patients were then randomized to either rescue PTCA or conservative therapy (36).

The trial found a mortality rate with rescue PTCA of 5.2% versus 9.9% if treated conservatively (not significant). The combined end-point of death or congestive heart failure at 30 days was 6.5% with rescue PTCA versus 16.4% with conservative therapy - a statistically significant result. Thus, rescue PTCA within 8 h of a first anterior myocardial infarction after *failed* thrombolysis appears to reduce mortality and congestive heart failure. Because there was no improvement in resting ejection fraction, the mechanism of these improvements is unclear.

4.10 DEFERRED ADJUNCTIVE CORONARY ANGIOPLASTY

Following myocardial infarction a positive exercise test is believed to have survival implications (37-41), although even here the studies are not unanimous (42-45). A recent analysis of the GISSI-2 (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto miocardico II) database (over 10,000 patients) revealed that the presence of a positive exercise test following thrombolysed myocardial infarction did not influence survival or nonfatal reinfarction after hospital discharge (46,47).

As for the risk of *nonfatal reinfarction* following an acute coronary syndrome, the exercise test interestingly appears to lack predictive value. In fact, a study by Théroux et al (38) showed that 5% of the group with a positive test later had another infarction or unstable angina compared with 10% of those with a negative test. Dwyer et al (48) could not demonstrate any predictive value for reinfarction with the exercise test in 866 patients with a one year follow-up.

Two large studies compared the strategy of deferred adjunctive angioplasty (PTCA done within the first week after AMI treated successfully with thrombolysis) with a more conservative approach awaiting clinical signs of recurrent ischemia before intervention.

The TIMI II main trial randomized patients to catheterization and prophylactic delayed adjunctive angioplasty 18 to 48 h after infarction or to conservative therapy (no intervention unless clinical indication of high risk). After one year of follow-up, both groups were similar in mortality and reinfarction rate (30,31).

The SWIFT (Should We Intervene Following Thrombolysis) trial randomized 800 patients after intravenous thrombolysis with streptokinase to either deferred adjunctive PTCA or conservative therapy. Similarly, they found no benefit of deferred adjunctive angioplasty for mortality or left ventricular function compared with the watchful waiting strategy (49).

Michels and Yusef's (14) meta-analysis also looked at adjunctive strategies of PTCA after thrombolysis, including immediate, early and delayed post-PTCA. This confirmed no clear evidence of additional benefit of the routine performance of PTCA at any time after thrombolysis versus waiting for clinical signs of ischemia.

4.11 RECOMMENDATIONS

4.11.1 Primary coronary angioplasty is a safe and efficacious alternative to intravenous thrombolysis for the treatment of AMI in centres with the resources of a 24 h available catheterization laboratory and experienced staff.

Grade: A

Level: I

4.11.2 Primary coronary angioplasty is recommended and is the treatment of choice in patients presenting with AMI complicated by cardiogenic shock.

Grade: C

Levels: III, IV and V

4.11.3 Primary coronary angioplasty is recommended and the treatment of choice in patients in whom thrombolytic therapy is contraindicated.

Grade: C

Level: IV

4.11.4 Primary coronary angioplasty in elderly patients can be conducted with an acceptable risk in experienced hands.

Grade: C

Level: IV

4.11.5 Patients with prolonged chest pain and nondiagnostic electrocardiogram changes should be treated as though they have unstable angina pectoris. They should receive urgent catheterization with a view to culprit lesion PTCA or bypass surgery if attempts to stabilize medically fail.

Grade: C

Level: V

4.11.6 Routine performance of immediate adjunctive PTCA after successful intravenous thrombolysis is not recommended.

Grade: A

Level: I

4.11.7 Rescue coronary angioplasty is recommended in patients presenting with evidence of failure of intravenous thrombolysis for the treatment of first anterior myocardial infarction. The role of rescue PTCA in other types of infarctions and other clinical scenarios requires clarification. A major limitation of rescue PTCA remains the lack of a sensitive and specific measure of the success or failure of thrombolysis at the bedside.

Grade: B

Level: II

4.11.8 Routine performance of deferred adjunctive coronary angioplasty after successful intravenous thrombolysis is not recommended.

Grade: A

Level: I

REFERENCES

1. Meyer J, Merx W, Don R, et al. Sequential interventional procedure after intracoronary thrombolysis: balloon dilatation, bypass surgery and medical treatment. Int J Cardiol 1985;7:281-93.

2. Hartzler GO, Rutherford BD, McConahay DR, et al. Percutaneous transluminal coronary angioplasty with and without thrombolytic therapy for treatment of acute myocardial infarction. Am Heart J 1983;106:965-73.

3. Holmes DR Jr, Smith HC, Vlietstra RE, et al. Percutaneous transluminal coronary angioplasty alone or in combination with streptokinase therapy during acute myocardial infarction. Mayo Clin Proc 1985;60:449-56.

4. OâKeefe JH Jr, Rutherford BD, McConahay DR, et al. Early and late results of coronary angioplasty without antecedent thrombolytic therapy without antecedent thrombolytic therapy for acute myocardial infarction. Am J Cardiol 1989;64:1221-30.

5. OâKeefe JH Jr, Bailey WL, Rutherford BD, Hartzler GO. Primary angioplasty for acute myocardial infarction in 1,000 consecutive patients. Results in an unselected population and high-risk subgroups. Am J Cardiol 1993;72:107G-15G.

6. OâNeill WW, Brodie BR, Ivanhoe R, et al. Primary coronary angioplasty for acute myocardial infarction (the Primary Angioplasty Registry). Am J Cardiol 1994;73:627-34.

7. Brodie BR, Grines CL, Ivanhoe R, et al. Six-month clinical and angiographic follow-up after direct angioplasty for acute myocardial infarction. Final results from the Primary Angioplasty Registry. Circulation 1994;25:156-62.

8. OâNeill WW, Timmis GC, Bourdillon PD, et al. A prospective randomized clinical trial of intracoronary streptokinase versus coronary angioplasty for acute myocardial infarction. N Engl J Med 1986;314:812-8.

9. Ribeiro EE, Silva LA, Carneiro R, et al. Randomized trial of direct coronary angioplasty versus intravenous streptokinase in acute myocardial infarction. J Am Coll Cardiol 1993;22:376-80.

10. Gibbons RJ, Holmes DR Jr, Reeder GS, Bailey KR, Hoppenspirger MR, Gersh BJ. Immediate angioplasty compared with the administration of a thrombolytic agent followed by conservative treatment for myocardial infarction. N Engl J Med 1993;328:685-91.

11. de Boer MJ, Hoorntje JC, Ottervanger JP, Reiffers S, Suryapranata H, Zijlstra F. Immediate coronary angioplasty versus intravenous streptokinase in acute myocardial infarction: left ventricular ejection fraction, hospital mortality and reinfarction. J Am Coll Cardiol 1994;23:1004-8.

12. Grines CL, Browne KF, Marco J, et al. A comparison of immediate angioplasty with thrombolytic therapy for acute myocardial infarction. N Engl J Med 1993;328:673-9.

13. OâNeill WW, Zijlstra F, Suryapranata H, Timmis GC, Grines CL. Meta-analysis of the PAMI and Netherlands randomized trials of primary angioplasty versus thrombolyic therapy of acute myocardial infarction. Circulation 1993;88(Suppl):I106. (Abst)

14. Michels KB, Yusuf S. Does PTCA in acute myocardial infarction affect mortality and reinfarction rates? A quantitative overview (meta-analysis) of the randomized clinical trials. Circulation 1995;91:476-85.

15. DeWood MA, Fisher MJ. Direct PTCA versus intravenous rt-PA in acute myocardial infarction: preliminary results from a prospective, randmized trial. Circulation 1989;80(Suppl II):II418. (Abst)

16. Elizaga J, Garcia EJ, Delcan JL, et al. Primary coronary angioplasty versus systemic thrombolysis in acute anterior myocardial infarction: in-hospital results from a prospective randomized trial. Circulation 1993;88(Suppl I):I411. (Abst)

17. Weaver WD, Litwin PE, Martin JS. Use of direct angioplasty for treatment of patients with acute myocardial infarction in hospital with and without on-site cardiac surgery. Circulation 1993;88:2067-75.

18. Reeder GS, Bailey KR, Gersh BJ, Holmes DR Jr, Christianson J, Gobbons RJ. Cost comparison of immediate angioplasty versus thrombolysis followed by conservative therapy for acute myocardial infarction: a randomized prospective trial. Mayo Clin Proc 1994;69:5-12.

19. Hibbard MD, Holmes DR Jr, Bailey KR, Reeder GS, Bresnahan JF, Gersh BJ. Percutaneous transluminal coronary angioplasty in patients with cardiogenic shock. J Am Coll Cardiol 1992;19:639-46.

20. Lee L, Erbal R, Brown TM, Laufer N, Meyer J, OâNeill WW. Multi-center registry of angioplasty therapy of cardiogenic shock: initial and long-term survival. J Am Coll Cardiol 1991;17:599-603.

21. Seydoux C, Goy JJ, Beuret P, et al. Effectiveness of percutaneous transluminal coronary angioplasty in cardiogenic shock during acute myocardial infarction. Am J Cardiol 1992;69:968-70.

22. Gacioch GM, Ellis SG, Lee L, et al. Cardiogenic shock complicating acute myocardial infarction: the use of coronary angioplasty and the integration of the new support devices into patient management. J Am Coll Cardiol 1992;19:647-53.

23. Moosvi AR, Khaja F, Villanueva L, Gheorghiade M, Douthat L, Goldstein S. Early revascularization improves survival in cardiogenic shock complicating acute myocardial infarction. J Am Coll Cardiol 1992;19:907-14.

24. Bengston JR, Kaplan AJ, Pieper KS, et al. Prognosis in cardiogenic shock after acute myocardial infarction in the interventional era. J Am Coll Cardiol 1992;20:1482-9.

25. Feldman T, Hinkle RC, Ziegler JW. Direct percutaneous transluminal coronary angioplasty for patients with exclusions from thrombolysis. Am Heart J 1994;127:1220-5.

26. Himbert D, Juliard JM, Steg PG, et al. Primary coronary angioplasty for acute myocardial infarction with contraindication to thrombolysis. Am J Cardiol 1993;71:377-81.

27. Topol EJ, Califf RM, George BS, et al. A randomized trial of immediate versus delayed elective angioplasty after intravenous tissue plasminogen activator in acute myocardial infarction. N Engl J Med 1987;317:581-8.

28. Immediate vs delayed catheterization and angioplasty following thrombolytic therapy for acute myocardial infarction. TIMI II A results. The TIMI Research Group. JAMA 1988;260:2849-58.

29. Baim DS, Braunwald E, Feit P, et al. The thrombolysis in myocardial infarction (TIMI) Trial Phase II: additional information and perspectives. J Am Coll Cardiol 1990;15:1188-92.

30. Williams DO, Braunwald E, Knatterud G, et al. One-year results of the Thrombolysis in Myocardial Infarction Investigation (TIMI) phase II trial. Circulation 1992;85:533-42.

31. Rogers WJ, Baim DS, Gore JM, et al. Comparison of immediate invasive, delayed invasive and conservative strategies after tissue-type plasminogen activator. Results of the thrombolysis in myocardial infarction (TIMI) Phase II-A Trial. Circulation 1990;81:1457-76.

32. Simoons ML, Arnold AE, Betriu A, et al. Thrombolysis with tissue plasminogen activator in acute myocardial infarction: no additional benefit from immediate percutaneous coronary angioplasty. Lancet 1988;i:197-203.

33. Arnold AE, Simoons ML, Van de Werf F, et al. Recombinant tissue-type plasminogen activator and immediate angioplasty in acute myocardial infarction. Circulation 1992;86:111-20.

34. Ellis SG, Van de Werf F, Ribeiro-deSalva E, Topol EJ. Present status of rescue cornary angioplasty: current polarization of opinion and randomized trials. J Am Coll Cardiol 1992;19:681-6.

35. Belenkie I, Traboulsi M, Hall CA, et al. Rescue angioplasty during myocardial infarction has a beneficial effect on mortality: a tenable hypothesis. Can J Cardiol 1992;8:357-62.

36. Ellis SG, da Silva ER, Heyndrickx GR, et al. Randomized comparison of rescue angioplasty with conservative management of patients with early failure of thrombolysis for acute anterior myocardial infarction. Circulation 1994;90:2280-4.

37. Sami M, Kraemer H, DeBusk RF. The prognostic significance of serial exercise testing after myocardial infarction. Circulation 1979;60:1238-46.

38. Theroux P, Waters DD, Halphen C, Debaisieux J, Mizgala HF. Prognostic value of exercise testing soon after myocardial infarction. N Engl J Med 1979;301:341-5.

39. Waters DD, Bosch X, Bouchard A, et al. Comparison of clinical variables and variables derived from a limited predischarge exercise test as predictors of early and late mortality after myocardial infarction. J Am Coll Cardiol 1985;5:1-8.

40. Rogers WJ, Schwartz KM, Turner JD, et al. Prediction of survival and functional status post-myocardial infarction by limited exercise testing prior to hospital discharge. Clin Res 1979;27:773A.

41. Starling MR, Crawford MH, Kennedy GT, OâRourke RA. Exercise testing early after myocardial infarction: predictive value for subsequent unstable angina and death. Am J Cardiol 1980;46:909-14.

42. Krone RJ, Gillespie JA, Weld FM, Miller JP, Moss AJ, and The Multicentre Postinfarction Research Group. Low-level exercise testing after myocardial infarction: usefulness in enhancing clinical risk stratification. Circulation 1985;71:80-9.

43. Madsen EB, Gilpin E. How much prognostic information do exercise test data add to clinical data after acute myocardial infarction? Int J Cardiol 1983;4:15-22.

44. Madsen EB, Gilpin E, Ahnve S, Henning H, Ross J. Prediction of functional capacity and use of exercise testing for predicting risk after acute myocardial infarction. Am J Cardiol 1985;56:839-45.

45. Williams WL, Nair RC, Higginson LAJ, Baird MG, Allan K, Beanlands DS. Comparison of clinical and treadmill variables for the prediction of outcome after myocardial infarction. J Am Coll Cardiol 1984;4:477-86.

46. Volpi A, DeVita C, Franzosi MG. Determinants of 6-month mortality in survivors of myocardial infarction after thrombolysis: results of the GISSI-2 data base. Circulation 1993;88:416-29.

47. Volpi A, DeVita C, Franzosi MG, et al. Predictors of nonfatal reinfarction in survivors of myocardial infarction after thrombolysis: results of the Gruppo Italiano per lo Studio della Sopravvivenze nell'Infarto Miocardico (GISSI-2) data base. J Am Coll Cardiol 1994;24:608-15.

48. Dwyer EM, McMaster P, Greenberg H, Multicenter Postinfarction Research Group. Nonfatal cardiac events and recurrent infarction in the year after acute myocardial infarction. J Am Coll Cardiol 1984;4:695-702.

49. SWIFT trial of delayed elective intervention v conservative treatment after thrombolysis with anistreplase in acute myocardial infarction. SWIFT (Should We Intervene Following Thrombolysis?) Trial Study Group. BMJ 1991;302:555-60.

50. Rothbaum DA, Linnemeier TJ, Landin RJ, et al. Emergency percutaneous transluminal coronary angioplasty in acute myocardial infarction. A 3 year experience. J Am Coll Cardiol 1987;10:264-72.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 5: Rates of cardiac catheterization, coronary angioplasty and coronary artery bypass surgery in Canada

Lyall AJ Higginson MD FRCPC, C David Naylor MD DPhil FRCPC

This portion of the consensus conference examines the rates of cardiac catheterization, coronary angioplasty and coronary artery bypass grafting (CABG) surgery in Canada. The Canadian Cardiovascular Society has regularly surveyed cardiac catheterization laboratories and surgical programs across the country since 1988, with published data available for 1988 and 1991 (1,2). The survey has been updated by the Society and forms the basis for this portion of the report. Waiting lists were also surveyed and, along with other published information, led to a discussion of the importance of ongoing collection of accurate information.

5.1 CARDIAC CATHETERIZATION

In 1993, 76,920 cardiac catheterizations were performed in Canada for a rate of 284/100,000 total population (Table 5.1). This rate increased 11% from 1991. The rate continues to be highest in Nova Scotia/Prince Edward Island at 310/ 100,000. The greatest increase from 1991 was in Saskatchewan (Figure 5.1). The longest wait for elective cardiac catheterization continues to be in Quebec with a mean wait of 14.9 weeks, slightly more than in 1991 when it was 12.2 weeks. The mean length of wait for elective cardiac catheterization in Canada was 9.1 weeks in 1993.

TABLE 5.1

Cardiac catheterizations in Canada in 1991 and 1993 and the number of patients awaiting elective catheterization by province

	Number of catheterizations/ province		Rate of cardiac catheterization/ 100,000 population		Number of centres		Patients awaiting elective cardiac catheterization/ 100,000 population		Mean length of wait (weeks)	
Province	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**
British Columbia	8180	9138*	249	278*	8	7	15	10*	6.9	4°
Alberta	7272	7819	285	307	4	4	10	9	4.2	7*
Saskatchewan	2118	2692	213	272	2	2	7	8	4.3	3.3
Manitoba	2970	2915	272	267	2	2	6	5	3.2	3.8
Ontario	22,898	23,292	227	231	13	14	14	21	6.7	7.9¤
Quebec	19,924	19,490¤	289	283½	14	14	23	18½	12.2	14.9¤
New Brunswick	1176	1814	238	251	1	1	12	14	5.7	3.0
Nova Scotia and Prince Edward Island	3236	3190	314	310	1	1	5	8	2.1	1.9
Newfoundland	1600	1566	280	276	2	1	9	9	6.4	7.1
Canada	69,374	76,920	256	284	46	46	15	15	8.5	9.1

**One centre did not report; °Two centres did not report; ½Four centres did not report; ¤Five centres did not report*

At present we do not have national data on the indications for cardiac catheterization. In the absence of valvular heart disease, serious arrhythmias and unexplained ventricular dysfunction, the majority of angiograms are performed with a view to revascularization by an appropriate method, where indicated. Angiography is also performed in some cases to assess prognosis and to confirm coronary anatomy where other clinical assessment has not been sufficiently definitive. Finally, some angiograms are performed in follow-up assessment of patients with prior revascularization, in particular percutaneous transluminal coronary angioplasty (PTCA). Indication data would be very helpful in assessing the outcomes of revascularization techniques in the long term, and in interpreting the important relationship of angiography to revascularization decision-making.

5.2 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

During 1993 17,487 PTCAs were performed in Canada for an average rate of 64/100,000 (Table 5.2). This rate increased from 54 in 1991, a 19% increase. The highest rates in Canada averaged 75 to 80/100,000 in British Columbia, Alberta, Saskatchewan, Quebec and New Brunswick; Ontario and Newfoundland had lower PTCA rates at 47 and 45/100,000, respectively. All provinces showed growth in PTCA rates, as illustrated in Figure 5.2. The mean waiting time for elective PTCA decreased from 1991 when it was 9.2 weeks, to 5.2 weeks in 1993.

5.3 CORONARY ARTERY BYPASS GRAFTING

In 1991, the average rate of CABG for Canada was 50/100,000. In 1993, this had increased by 12% to 56/100,000 with the highest rate in Nova Scotia/Prince Edward Island, followed by Ontario and British Columbia (Figure 5.3). As of December 31, 1991, the mean length of wait for elective CABG in Canada was 21.3 weeks, with the longest wait being in Quebec (Table 5.3).

As demonstrated by Table 5.3, there has been a significant reduction in waiting times for all provinces with the most improvement occurring in Ontario and Quebec. There continues to be significant variation in the use of CABG and of PTCA from province to province (Figure 5.4). PTCA is more frequently performed in all provinces except Ontario and Newfoundland, while in British Columbia, Alberta, Saskatchewan, Quebec and New Brunswick there is a substantially higher rate of PTCA than of CABG. On average across the country PTCA is performed more frequently than CABG.

It has been suggested that the rate of cardiac catheterization is an important factor in driving the rate of CABG and percutaneous angioplasty. When we examine the ratio of catheterization to CABG (Figure 5.5) and the ratio of catheterization to PTCA (Figure 5.6), there appears to be marked discordance across the country. However, when we combine the procedures and look

at the ratio of catheterization to revascularization (Figure 5.7), the discrepancies are less extreme. On average, across the country just over two cardiac catheterizations are performed for every revascularization procedure, be it percutaneous angioplasty or CABG.

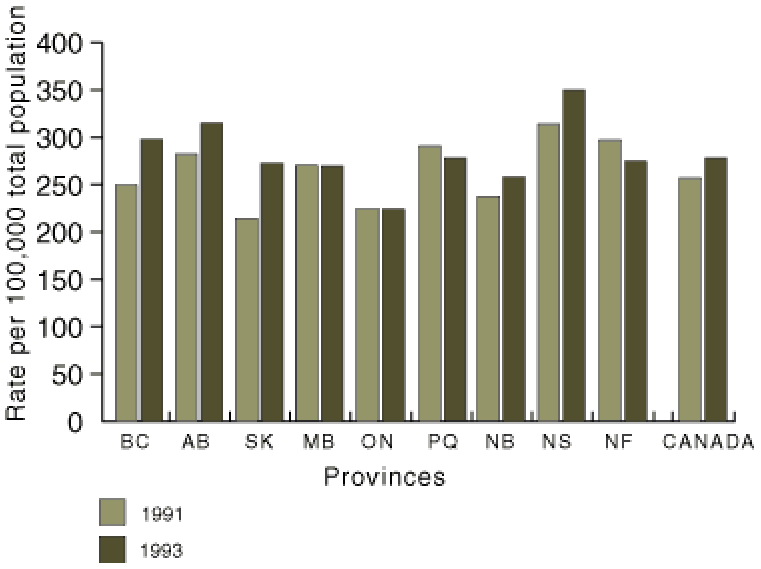


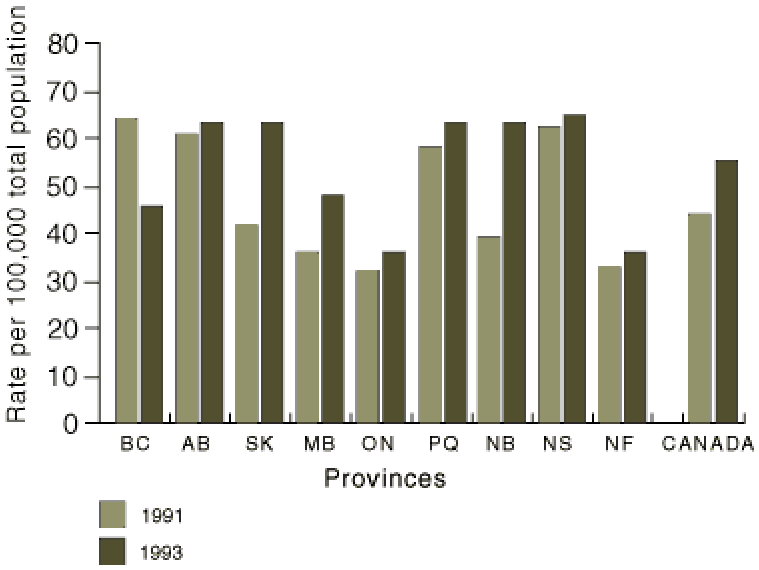
TABLE 5.2

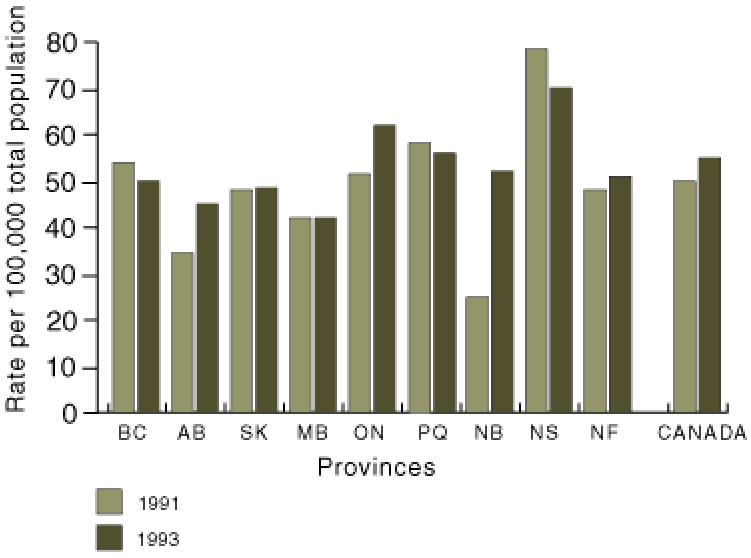
PTCAs in Canada in 1991 and 1993 and the number of patients awaiting elective PTCA by province

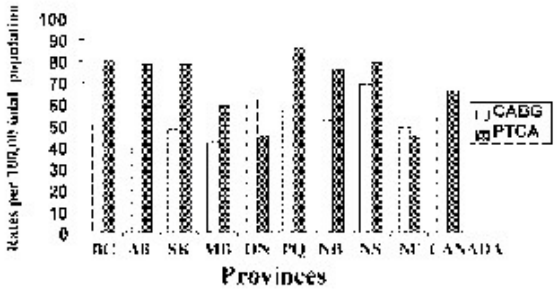
	Number of PTCAs/ province		Rate of PTCA/100,000 population		Number of centres		Patients awaiting elective PTCA/ 100,000 population		Mean length of wait (weeks)	
Province	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**
British Columbia	1849	2610	56	80	4	4	6	5	9.1	6*
Alberta	1921	1976	76	78	4	4	6	3*	7.7	5.9*
Saskatchewan	506	769	51	78	2	2	1	2	4.4	2.5
Manitoba	481	587	44	54	2	2	4	2	10.2	3.8
Ontario	3809	4692	38	47	9	9	2	3	4.5	5.7
Quebec	4718	5337°	68	77°	12	12	5	4°	13.5	4.6½
New Brunswick	342	549	48	76	1	1	2	1	2.1	2.0
Nova Scotia and Prince Edward Island	765	715	74	69	1	1	4	4	6.7	2.6
Newfoundland	222	257	40	45	1	1	2	3	12.8	8.6
Canada	14,617	17,487°	54	64	37	36	4	3	9.2	5.2

**One centre did not report; °Three centres did not report; ½Five centres did not report. PTCA Percutaneous transluminal coronary angioplasty*

In summary, since this survey was first initiated by the Canadian Cardiovascular Society, there has been a moderate increase in cardiac catheterization and CABG across the country. PTCA has increased to a greater extent and is now a more common strategy for revascularization than CABG. There are very significant regional variations across the country. Exploring the reasons for these rate variations and their impact on outcomes will help us to address concerns about variations in access and in procedural waiting times across the country.







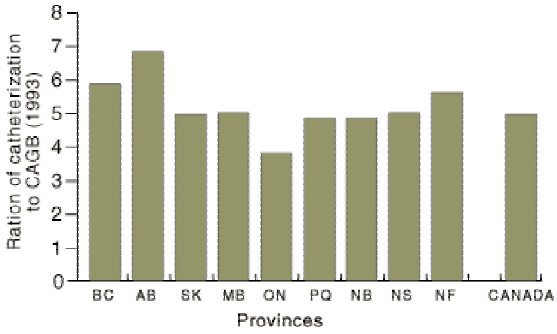


TABLE 5.3

CABG in Canada in 1991 and 1993 and the number of patients awaiting elective CABG by province

	Rate of CABG/ 100,000 population		Number of centres doing surgery		Average number of CABG/centre		Patients awaiting elective surgery/ 100,000 population		Mean length of wait (weeks)	
Province	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**	**1991**	**1993**
British Columbia	53	50	4	4	438	412	15	7*	17.9	9*
Alberta	34	45	3	3	288	384	16	13	18.2	10.3
Saskatchewan	47	48	2	2	233	237	9	7*	15.2	15.2°
Manitoba	42	42°	2°	2°	231	°	15	°	12.9	12.9°
Ontario	52	64	9	9	582	718	10	9	9.6	13.6
Quebec	52	51°	10	10	358	350°	17	9°	33.5	9½
New Brunswick	25	52	1	1	179	374	12	8	19.3	1.0
Nova Scotia and Prince Edward Island	78	69	1	1	808	624	39	8	25.9	12.9
Newfoundland	47	49	1	1	270	280	19	18	25.9	6.6
Canada	50	56	33	33	413	440	14	9	21.3	10.6

**One centre did not report; °Two centres did not report; ½Three centres did not report. CABG Coronary artery bypass graft*

5.3.1 Patterns of coronary artery bypass use

The data for monitoring rates of revascularization in Canada come from surveys such as that conducted by the Canadian Cardiovascular Society, computer databases, hospital discharge abstracts or Medicare claims. There are considerable problems with each of these mechanisms, underscoring the necessity of a national registry. With the limited information available, however, some conclusions can be developed regarding the changing patterns of revascularization and particularly the use of CABG.

Since the early 1980s there has been an increase in CABG rates from 30 to close to 60/100,000, but there has also been a change in the type of patient bypassed. Christakis et al (3) outlined the changing pattern of CABG at the University of Toronto. Between 1982 and 1986, the proportion of patients over 70 years of age increased steadily from 2% to 7%. The proportion over 65 years of age grew from 14% in 1982 to 27% in 1986. Anderson and Lomas (4), using data from the Hospital Medical Records Institute, analyzed CABG in Ontario from 1979 to 1984. The rate among people 65 to 69 years of age doubled, and the rate among those over 70 years increased fivefold. The proportion of procedures in those over 65 years of age rose from 12.8% to 27.4%. In Manitoba from 1977 to 1984 the rate per 100,000 adults increased from 20 to 59 with a less pronounced growth among the elderly than in Ontario (5). Statistics Canada reported a 39% increase in the national rate of CABG from 1981 to 1987 (6); they also reported a significant increase in the frequency of revascularization among elderly people.

Another trend in CABG is to a higher incidence of reoperations. Morin and collaborators (7) reported 2750 open-heart procedures from the Royal Victoria Hospital in Montreal. Comparing the data from 1982 with those from 1987 they found that reoperations had increased from 6% to 9%, and this trend continues across the country. The other major change in bypass surgery is that a greater percentage of patients have unstable coronary syndromes.

In a recent analysis based on data from The Toronto Hospital for 1982 to 1996 (8), these findings were strongly supported. Measured as patients aged 70 years and over, the proportion of elderly patients rose from 10.0% in 1982-86 to 24.6% in 1992-96. There was a significant

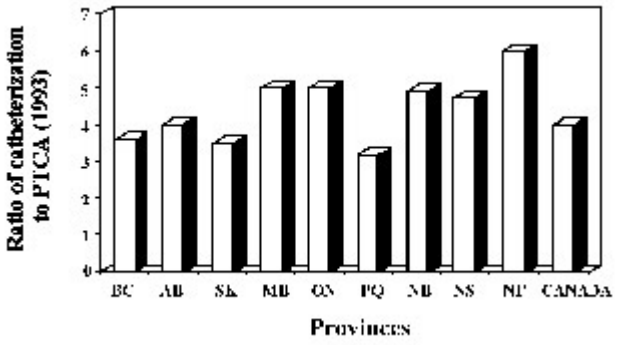
increase in reoperations overall, but this was most marked for patients over 70, where the percentage rose from 1.5% in 1982-86 to 6.9% in 1992-96.

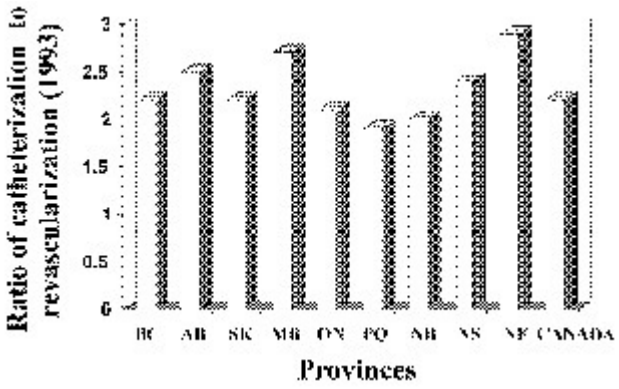
5.4 WHICH RATE OF REVASCULARIZATION IS RIGHT?

Other chapters of this consensus conference report also address the difficult question of determining the 'right' rate of coronary angiography and revascularization. Here, we briefly review some recent studies that have shed light on this issue.

The rates of all major coronary procedures in New York State are about twice as high as those in Ontario. A comparison of 1993 registry data from the two jurisdictions (9) showed that only 6% of CABG patients in Ontario versus 30% in New York State had limited coronary artery disease, defined as one or two vessel disease without involvement of the proximal left anterior descending artery. However, more patients in New York had left mainstem disease (23% versus 16%, $P<0.001$). In relative terms the differences were most dramatic among elderly persons. New York surgery rates among persons over 75 years of age with limited coronary artery disease were 17-fold higher than in Ontario. However, 90% of the persons with limited coronary anatomical disease in New York had moderate to severe angina before surgery.

A reasonable inference is that major increases in capacity and expansion of population-based service rates are associated with diminishing marginal returns. The Canadian approach - fixed budgets in a universal health care system and 'managed delay' with organized waiting lists - seems to promote more efficient use of resources, with patients receiving surgery primarily if they are likely to have life expectancy gain. However, restricted use of coronary angiography and revascularization leads to some implicit rationing with negative impacts on quality of life that affect primarily the elderly, and a certain proportion of patients at all ages with left mainstem disease are not detected and/or do not undergo surgery.





A different analysis based on Ontario registry data supports these arguments. Hux and Naylor (10) inferred degree of anticipated life expectancy gain for individual patients based on a meta-analysis of randomized trials comparing surgical with medical therapy for patients with chronic stable angina. They found that only 6% of 5058 Ontario patients undergoing isolated CABG in 1992-93 fell in the low benefit category - that is, patients for whom no long term survival advantage could be expected from early CABG. However, significantly more patients were in a high benefit category in hospitals serving areas with lower population-based rates of CABG. Analyzing the data by site of patient residence, there was an inverse relationship between marginal degree of life expectancy gains and the surgical rates for each country, particularly as rates rose above 90 to 100/100,000 adults (roughly 70 to 80/100,000 total population). On the other hand, the differences in profiles of patientsâ symptoms among regions were small, suggesting that higher rates of surgery might lead to better quality of life for patients with coronary disease, notwithstanding diminishing marginal returns from the standpoint of life expectancy gains.

The policy decision, as always, becomes one of trade-offs: given competing demands on scarce health care resources, at what point do the marginal returns of revascularization become low enough that further investment in those services cannot be justified? How much is society willing to invest in life-enhancing medical procedures, as opposed to investments in services and programs outside of the health care system that also improve quality of life for Canadians?

5.5 ARE THE UTILIZATION DATA VALID?

Data collected for this consensus report come primarily from a survey, with an inability to validate its accuracy and precision. Data were corroborated with the provincial registry information in Ontario and in British Columbia, but registry corroboration was not available in the other provinces. For denominators, census data were used, and there is little problem in interpolation between census years. As outlined by Naylor et al (11), there are three main sources of error in determining the numerator (number of procedures) from survey or from administrative data. These errors include miscoding a procedure. A classic example of this is that in many centres PTCA is performed at the same time as diagnostic cardiac catheterization. Unless this is examined carefully and coded appropriately, comparisons cannot be made between provinces. The second error is residence-related, with inappropriate allowance for procedures performed out of province or outside of Canada. Several centres in Canada supply services to out-of-province patients making appropriate interprovincial comparisons difficult. For example, Ontario residents account for 95% of all open-heart procedures performed in hospitals in that province. Four to five per cent come from other provinces, notably Quebec, while referrals from northwestern Ontario frequently go to Manitoba. Similarly, patients from southeastern British Columbia are usually referred to Alberta. When comparing the growth of CABG over time in Canada, it is important to know that New Brunswick did not have a CABG facility before 1991.

Accurate data on procedure rates for revascularization are tremendously important for the allocation of limited resources. The best way to collect information accurately is with a national

registry, where data are prospectively collected and verified via manoeuvres commonly applied in clinical research: standard definitions, random double-checking of records and, if necessary, the over-reading of angiograms and chart audits. Such a registry is now available in Ontario and British Columbia for CABG, and is being developed for PTCA and coronary angiography, but a nationally coordinated registry must be developed. Registration of all patients undergoing cardiac catheterization is underway in Alberta in a project called APPROACH (Alberta Provincial Project on Outcome Assessment in Coronary Heart Disease). Data are entered into computers in each catheterization laboratory in the province, connected to a central server; standardized coronary and clinical definitions are used. The focus of this observational database is the assessment of clinical decision-making, clinical outcomes, and long term cost of diagnosis and treatment of all ischemic syndromes.

5.6 ARE THE WAITING LIST DATA VALID?

Waiting times for CABG were most pronounced between 1987 and 1989 at the time of the first Canadian Cardiovascular Society survey (2). Survey data from 1991 and 1993 show improvements. Nevertheless, queues persist and access continues to be a problem in our Medicare system. The existence of long waiting lists for cardiac procedures has been noted by the American Medical Association and has been used to warn the American population of what might result from the adoption of universal health insurance patterned on the Canadian model (12). However, it may be that queue-based allocation of services, if based on objective criteria with selective delay, is superior to price-based rationing.

The Canadian Cardiovascular Society surveys have been cross-sectional and do not accurately capture the natural history of a waiting list. In the survey surgical directors were asked when elective patients were typically being booked for open heart surgery. This approach does not capture the variability inherent in the mean waiting time and does not allow for differing definitions of Îelectiveâ. This type of analysis is also subject to a type of prevalence/incidence bias in that the most severely ill patients may either die or be moved to the head of the queue (13). The analysis cannot adequately capture or calculate hazard rates, i.e., risk of death, myocardial infarction or other discreet adverse events per unit of time waiting. It is vital for prospective registry data to reflect accurately the natural history of the

disease, from the time of coronary angiography or, better, from the time a coronary angiogram is booked, to completion of the revascularization procedure (13). This information is being collected in some provinces, but needs to be nationally coordinated to provide some idea of the true magnitude of waiting lists, and to assess how many patients get revascularized within an optimum time frame for their anatomical subset and anginal pattern.

Fortunately, deaths on the waiting list are rare, even though the waiting time is long and there are large numbers. Naylor et al (14) analyzed the experience with patients awaiting isolated CABG in the Ontario registry for 1991-93; there were 31 deaths among 8517 registrants, for a fatality rate of about 0.4%. It seems, therefore, that to save lives, a marked reduction in waiting times is necessary. On the other hand, the queue has a number of other burdens associated with it. CABG and PTCA are performed primarily to relieve symptoms. We need to examine how quality of life is impaired while on the waiting list. Second, it is important to assess the economic impact of a waiting list. There are hidden economic costs associated with waiting, including reduced productivity. Data also suggest that the longer the waiting time for persons who are out of work due to coronary symptoms, the lower the probability that such a person will return following revascularization. A societal perspective on the economics of the queue is sorely lacking. Finally, patients can convert from a stable to an unstable status while on the waiting list with associated morbidity, increased risk and a decrease in their potential benefit from revascularization.

The consensus from all of this is straightforward. There is an urgent need for a national registry to collect accurate, prospective data on cardiac catheterization, revascularization procedures and waiting times. Furthermore, the experience of persons waiting for revascularization can and must be studied, analyzed and summarized. This must be a priority for the Society and for our health care delivery system.

5.7 RECOMMENDATIONS

5.7.1 A national observational database should be established to monitor

- patient selection for revascularization;
- procedural waiting times and determinants of events on the queue;
- clinical and cost outcomes; and
- changing resource needs resulting from population ageing.

This should be a joint initiative among the Canadian Cardiovascular Society, the Heart and Stroke Foundation of Canada and the provincial ministries of health.

Grade: Consensus

5.7.2 Cardiac centres should separately log diagnostic cardiac catheterization, angioplasty and 'single-stage' (combined diagnostic and angioplasty) procedures.

Grade: Consensus

REFERENCES

1. Higginson LAJ, Cairns JA, Smith ER. Rates of cardiac catheterization, coronary angioplasty and coronary artery bypass surgery in Canada (1991). Can J Cardiol 1994;10:728-32.
2. Higginson LAJ, Cairns JA, Keon WJ, Smith ER. Rates of cardiac catheterization, coronary angioplasty and open-heart surgery in adults in Canada. Can Med Assoc J 1992;146:921-5.
3. Christakis G, Ivanov J, Weisel RD, et al. The changing pattern of coronary artery bypass surgery. Circulation 1989;80(Suppl I):I151-61.
4. Anderson, Lomas, et al Anderson GM, Lomas J. Monitoring the diffusion of a technology: coronary artery bypass surgery in Ontario. Am J Public Health 1988;78:251-4.
5. Roos LL, Sharp SM. Innovation, centralization and growth: coronary artery bypass graft surgery in Manitoba. Med Care 1989;27:441-52.
6. Peters S, Chagani K, Paddon P, et al. Coronary artery bypass surgery in Canada. Health Rep 1990;2:9-26.
7. Morin JE, Symes JF, Guerraty AJ, et al. Coronary artery bypass profile in Canada and the United States. Can J Cardiol 1990;6:319-22.
8. Ivanov J, Weisel RD, David TE, Naylor CD. Fifteen-year trends in risk severity and operative mortality in elderly patients undergoing coronary artery bypass graft surgery. Circulation. (In press) still in press??
9. Tu JV, Naylor CD, Kumar D, McNeil BJ, Hannan EL, and the Steering Committee of the Cardiac Care Network of Ontario. Coronary bypass surgery in Ontario and New York State: which rate is right? Ann Intern Med 1997;126:13-9.
10. Hux JE, Naylor CD and the Steering Committee of the Provincial Adult Cardiac Care Network of Ontario. Are the marginal returns of coronary artery surgery smaller in high rate areas? Lancet 1996;348:1202-7.

11. Naylor CD, Ugnat AM, Weinkauf D, et al. Coronary artery bypass grafting in Canada: what is its rate of use? Which rate is right? Can Med Assoc J 1992;146:851-8.

12. Carol RJ, Horn SD, Soderfeldt B, James BC, Malmberg L. International comparison of waiting times for selected cardiovascular procedures. J Am Coll Cardiol 1995;25:557-63.

13. Naylor CD. A different view of queues in Ontario. Health Aff (Millwood) 1991;10:110-28.

14. Naylor CD, Sykora K, Jaglal SB, Jefferson S, for the Steering Committee of the Adult Cardiac Care Network of Ontario. Waiting for coronary artery bypass surgery: population-based study of 8517 consecutive patients in Ontario, Canada. Lancet 1995;346:1605-70.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 6: Revascularization rates and waiting lists – An international perspective

Andrew Morris MD FACC ABIM, David Almond FRCPC

Cardiovascular mortality in North America and Europe is similar, ranging between 330 and 380/100,000 population; however, utilization rates and waiting times for cardiovascular procedures vary widely, suggesting that incidence of cardiovascular disease is not a major factor in driving these differences.

Regional differences have stimulated debate regarding the 'right rate' or the 'best rate' for the availability and use of medical and surgical resources. Unless these rate variations can be shown to correlate with outcome measures such as mortality, morbidity and quality of life, health care resource allocation is likely to be based on the assumption that lower rates are preferable to higher rates.

It appears that some of the variation in rates reflects differences in defining appropriateness for the performance of these procedures, as well as differences in the degree to which these definitions are accepted as operational guidelines. These variations, therefore, represent stylistic differences in medical practice that may represent compromises between local resources and local standards and expectations. If this is true, each of these compromises (or level of regional equilibration) may themselves be 'appropriate' on a regional basis. Debate likely will continue, therefore, among paying agencies, professionals, and the society at large regarding the best rate for their locale rather than the ideal, universal, best rate.

In this chapter we review some of the data regarding the application of coronary angiography, angioplasty and coronary artery bypass graft (CABG) surgery in several nations and in various regions of Canada and the United States.

6.1 INTERNATIONAL PROCEDURE RATES

In 1989/1990 annual bypass surgery rates ranged widely internationally, from a low of 16.2/100,000 population in Japan to 262/100,000 in the United States. Similarly, for the same time period coronary angioplasty ranged from 14/100,000 in Germany up to 85/100,000 in the United States.

Collins-Nakai et al (1) reported procedural rates in 1989/90 from nine countries. Cardiac catheterization rates (of which we assume the majority represented coronary angiography) are highest in the United States. Two three-country groups can be identified that have medium rates (about 250/100,000 population: Belgium, Canada and Germany) and low rates (about 110/100,000 population: The Netherlands, Sweden and the United Kingdom) compared with the United States rate. Within each group, however, there is a wide variation in the rates of both percutaneous transluminal coronary angioplasty (PTCA) (nearly fourfold) and CABG (nearly twofold) after angiography. These are differences both in the rate of revascularization per 100,000 population and in the proportion of postangiography patients proceeding to revascularization.

Within Europe in 1989/1990 rates of coronary angiography and the proportion of patients who are then referred to both PTCA and CABG were highest in Belgium and lowest in Germany. This may be explained, at least in part, by the Belgian system. Patients are free to see their family doctor or a private specialist, or go directly to an out-patient department or a hospital for direct admission. Physicians, for their part, are free to choose where to practice and which patients to see. A national body sets rates for both physicians and hospitals.

In 1989/1990 Canada occupied a middle ground in the rate of revascularization in the medium rate group. The range of the rate of revascularization in the low rate catheterization group,

however, was quite similar to that of the medium rate group. Although the low rate countries perform fewer angiograms, many more of their patients proceed to revascularization. For example, 17% of Canadian patients had PTCA after catheterization, versus 41% of Dutch patients. This is true, as well, for CABG. Although Canada is a medium rate catheterization country, the proportion of Canadian patients proceeding to PTCA was rather similar to that of the United States (ie, 17% versus 23%, respectively). The CABG rate in Canada, however, was far lower than that in the United States (18% versus 38% of catheterized patients).

Since the Nakai publication, detailed statistics for European countries in 1993 have been published (2). A summary of some of the data in this publication is shown in Figure 6.1. There have been major changes. German angiographic and revascularization rates exceeded those of France, Belgium and The Netherlands in 1993. Also in 1993 Canadian rates were very much on a par with most of western Europe. Precise figures for the United States in 1993 are not available, but cardiac catheterization rates were likely well in excess of 500/100,000 population.

6.1.1 Contributors to revascularization rate variations

6.1.1.1 Available revascularization centres: In general, there is a definite correlation between waiting times and the number of centres available for revascularization. In the case of surgery, these range from a low of seven in Sweden up to 826 in the United States. In terms of population, this represents 0.08 centres/100,000 population in Sweden, which has among the longest waiting times, as opposed to 0.33/100,000 in the United States, which has the shortest waiting time. The Canadian figure is 0.13 surgical centres/100,000. The number of centres, combined with the number of procedures performed in these facilities, accounts for the majority of waiting time differences. The number of procedures performed per centre is 516 in Canada compared with 797 in the United States. The procedure rate per 100,000 population in the United States compared with Canada is therefore 4:1, accounting for most, but not all, of the sixfold difference in waiting times between these two countries.

In the United States there is a strong association between the number of cardiac catheterization laboratories and the use of angiography in certain situations. This was shown to

be particularly true of postinfarction evaluation in the GUSTO (Global Utilization of Streptokinase and TPA for Occluded arteries) study (3). In a parallel study from Harvard analyzing angiography use after infarction from Medicaid data, large variations in use were seen between New York State and Texas, but outcomes were the same (4).

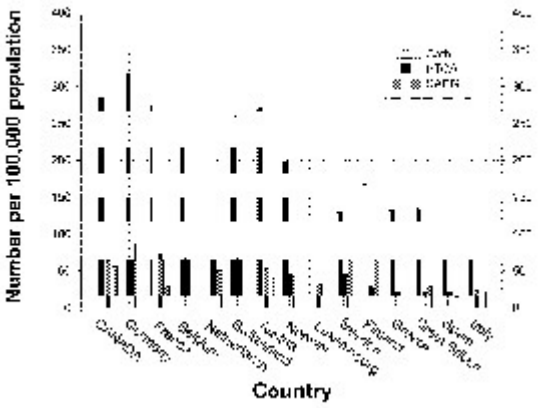
6.1.1.2 Physician considerations: In general, rate of use varies directly with the numbers of cardiovascular surgeons or cardiologists per 100,000 population. It also tends to be highest in countries with free market economies, greater resources and higher remuneration for physicians (1,5,6). If both are factors in a countryâs rate of use, the two are not always strongly linked. In the American Veterans Administration (VA) hospital system, physicians are essentially government employees, similar to the National Health System in the United Kingdom. But there is a fundamental difference: many cardiologists and cardiovascular surgeons in the VA system work at non-VA hospitals as well, and are paid from several sources, eg, VA, Medicare, etc. As discussed in section 6.3, waiting times in the VA system are closer to those of American Îfree marketâ hospitals than to the systems in Canada or the United Kingdom (5), perhaps because of influences from their non-VA practice and/or knowledge of practice standards in the community.

6.1.1.3 Funding mechanisms: Langa and Sussman (7) compared the combined rate of PTCA and CABG in California in 1983 with that of 1988, for patients covered by Medicaid, fee-for-service or health maintenance organizations (HMOs). The rate of revascularization increased slightly over the five-year interval for Medicaid patients. Fee-for-service and HMO-covered rates rose gradually between 1983 and 1985 and increased dramatically from 1985 to 1988. The adjusted odds ratios for revascularization of fee-for-service and HMO patients compared with Medicaid patients were 2.33 and 1.53, respectively. Whatever the explanation for the stable rate of revascularization in Medicaid patients during the study period, these data suggest that the mechanisms of funding for health care influence the rate at which procedures are performed.

The Group Health Association of America reported an analogous advantage for HMOs. A survey at HMOs was compared with United States national hospital discharge data (Figures

6.2,6.3). Although the figures are stratified only for age (above and below 65 years) the HMO utilization rates are less than half those seen with the national discharge data from American hospitals. The United States HMO cardiac catheterization and surgery rates of 499 and 185/100,000, however, are significantly higher than the Canadian rates for 1991 of 256 and 50/100,000 (8), respectively.

Although Canada has a single-payer national health care system, the managed care approach applied by HMOs is not part of the Canadian system, and cannot, therefore, account for the lower rate of use in Canada than in the United States. Canada, on the other hand, controls health care expenditures by limiting health care resources, rather than by micromanaging use. Even in United States HMOs, however, the rate of catheterization and CABG surgery remains far greater than in Canada. The United States HMO appears able to reduce use, compared with unmanaged care, but not to levels achieved in Canada. Whether these rates will tend to merge over time remains undetermined.



6.1.1.4 Socioeconomic considerations: Between 1983 and 1989, the largest growth in surgical revascularization occurred in the age group older than 75 years. This was true for both the United States and Canada, and one report suggests that variance in the size of the over 65 age groups accounts for 75% of the overall difference in revascularization rates between the two countries (9). This relative increase in older age groups may be due to two factors.

Improved surgical techniques could be qualifying more elderly CABG candidates, and, perhaps, a higher proportion of younger patients undergo balloon angioplasty and withdraw from the surgical pool. In younger patients in the United States, revascularization rates appear to increase with income, although studies have shown the incidence of cardiovascular disease to be highest in the lowest socioeconomic groups (9). This is not the case in Canada where, in fact, revascularization rates are highest in the poorest income group. This is somewhat different for elderly patients (greater than 75 years of age), where the highest revascularization rates are seen in the higher income groups in both the United States and Canada. However, in the United States, the lowest revascularization rates continue to be in the group with the lowest income. Nationally, there is a correlation between rank order in waiting times and rank order of the percentage of the gross national product spent on health care (5).

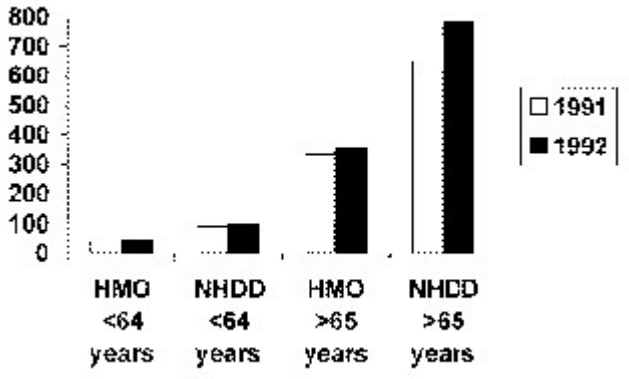
6.1.1.5 Regional 'styles' of practice: It appears that different countries have different 'styles' of practice in cardiovascular disease. These practice styles describe overall behaviour patterns, but even within countries, revascularization and catheterization rates vary significantly. Administrative data from Manitoba indicate that the rate of angiography is different in Winnipeg, Brandon and a number of rural regions (10). Similarly, striking differences in age-adjusted CABG referral rates were reported for Alberta, with more striking variation in women than in men (11). The magnitude of these differences is similar to those seen in international comparisons and remains unexplained. A study of regional patterns of revascularization after acute myocardial infarction (MI) in Ontario also found "significant and unexplained regional variations in the rate of use and waiting times for revascularization". These differences can be partly explained by the fact that the diagnostic use of angiography in unstable angina is greater in cities where angiographic facilities are available.

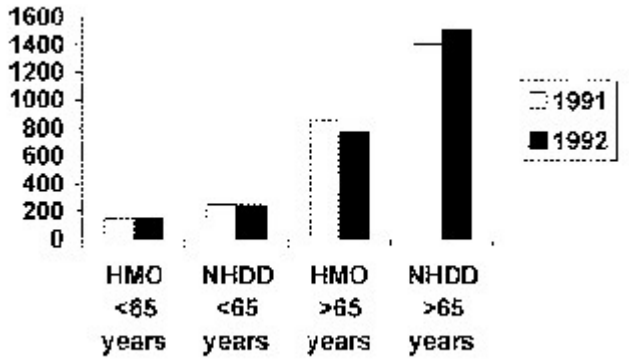
6.1.2 Literature on international comparisons

6.1.2.1 Sweden and the United States: Bernstein et al (12) and Bengtson et al (13) emphasize that the criteria for the "appropriateness of use of cardiovascular procedures" is not universal and must be defined within "different countries or regions". Applying Swedish and American

criteria to two small populations of patients undergoing coronary angiography and CABG in New York State, Bernstein observed that the former were judged to be 'appropriate' by 75% and 49% of the American and Swedish criteria, respectively, and the latter by 93% and 57%. According to Swedish criteria, therefore, about half of each of these procedures were performed without a clear indication. By American criteria, however, most procedures were felt to have been appropriate. Bengtson observed that in Sweden the majority of patients undergoing angiography and CABG had "chronic stable angina that is influencing the quality of their lives despite optimal medical management" (ie, for clinical criteria). In the United States, on the other hand, angiography is performed more often "on patients with insignificant disease".

6.1.2.2 United States and United Kingdom: Brook and colleagues (14) applied Rand Corporation criteria for appropriateness of angiography and CABG to case scenarios presented to panels of United States and United Kingdom physicians. The British panel was more conservative than their American colleagues and was less likely to rate either procedure as appropriate. The authors note that these groups of physicians have similar training but "practice medicine in different systems of health care and their patients have different cultural and economic attitudes toward health". Both panels tended to concur when "there was good evidence based on rigorous clinical trials". However, British physicians were more reluctant to proceed when "clear evidence" of benefit was lacking. As well, British panelists tended not to proceed with angiography or CABG "when the patient was on less than maximum tolerated medication".





6.1.3 United States versus Canada

Anderson and Lomas (15) reported CABG rates per 100,000 from California, New York, British Columbia, Manitoba and Ontario of 112.5, 97.4, 63.2, 53.2 and 66.2, respectively. These rates reveal a 47/100,000 person difference in the rate at which CABG is performed in California compared with the three Canadian provinces. Even after adjusting for age, a 50/100,000 difference remains between California and Canada. The authors concluded that these differences in rates "are not primarily driven by differences in disease prevalence, but rather by differences in treatment practices".

Rouleau et al (6) and Mark et al (16) compared the American and Canadian approach to the care of patients with acute MI who participated in the SAVE (Survival And Ventricular Enlargement) and GUSTO trials, respectively. United States patients in SAVE had rates of angiography, PTCA and CABG that were 1.6, 2.3, and 17.1 times, respectively, those in Canada. The differences in revascularization rates were related to higher rates of PTCA per angiogram performed, rather than increased rates of both PTCA and CABG for a given number of angiograms. This observation led the authors to conclude that the Canadian approach was "more conservative" and that "physicians in both countries approach the treatment of more severe coronary artery disease similarly".

The GUSTO trial results were similar to those reported in SAVE. Post-MI in-hospital angiography rates in the United States and Canada were 72% versus 25%, respectively. PTCA

and CABG rates were also higher in the United States (29% versus 11% and 14% versus 3%, respectively). Angiography was performed earlier in the United States than in Canada (median four versus 11 days), as was revascularization (median five versus 16 days). In spite of marked differences in the rates of use of angiography and revascularization, the only differences in outcome were a reduction in the frequency of activity-limiting angina in American patients in SAVE and a small enhancement in the quality of life in patients in GUSTO.

6.2 DO DIFFERENT REGIONS ADHERE TO DIFFERENT TREATMENT STANDARDS?

One explanation for the variation in cardiovascular procedure rates may be differences in the definitions of "appropriateness" for the use of various procedures and/or variations in the degree to which physicians adhere to their regional criteria for appropriateness (assuming that these criteria have been made explicit). Rates of appropriateness for coronary angiography, PTCA and CABG in New York State, both for the procedures themselves and for disease-specific conditions, have been reported (17-23). These authors observed that 64%, 35% and 82% of these procedures, respectively, were judged to be "appropriate and crucial". Another 12%, 23% and 8%, respectively, were felt to be "appropriate". The remainder, 24%, 42% and 9%, respectively, were graded as "uncertain" or "inappropriate".

Patients with unstable angina underwent angiography for "appropriate and crucial" indications 88% to 91% of the time. Patients with acute MI and/or chronic stable angina pectoris met these criteria about half as often.

These data suggest that, at least in New York State, variations in procedure rates are related to factors other than the accepted medical indications for their performance. Similar results have been obtained from studies of a wide variety of medical and surgical procedures. It is interesting, however, that for the most invasive and expensive procedure, CABG, the degree of inappropriateness was least.

6.3 WAITING LISTS FOR CARDIOVASCULAR PROCEDURES

Data regarding both Canadian and international waiting periods for diagnostic and therapeutic cardiovascular procedures are limited. Collins-Nakai et al (1) reported data from nine countries for 1990. The average waiting period for cardiac catheterization varied from almost no wait to 3.4 months in Germany. Those for PTCA and CABG varied from two to 12 weeks and three weeks to eight months, respectively. In Canada, these three waiting periods were 8.5 weeks, 11 weeks and 22.6 weeks, respectively. In the United States, no waiting periods were reported for any procedure. Recent debates in the United States regarding health care reform described Canadian waiting periods as being consistent with national health care systems in general and not in the best interest of Americans.

Higginson et al (8,24) reported Canadian waiting periods for the same three procedures in 1988 and 1991. The average Canadian waiting periods for cardiac catheterization, PTCA and CABG were 8.5 weeks, 9.2 weeks and 21.3 weeks, respectively. These data were nearly identical to those reported by Collins-Nakai et al for Canada in 1990. Higginson provided provincial as well as national data. The provincial average waiting lists for these three procedures varied from 2.1 to 12.2 weeks, 2.1 to 13.5 weeks and 9.6 to 33.5 weeks, respectively. Variations in waiting periods seen in international comparisons are also seen within Canada (and, presumably, within other countries as well).

An "International comparison of waiting times for selected cardiovascular procedures" was reported by Carroll et al (5). These authors surveyed directors of cardiac catheterization laboratories and cardiac surgical programs at 100 randomly selected hospitals in the United States, the United Kingdom, Canada and Sweden. Each participant was asked to estimate the actual waiting period encountered in their locale for each of two case scenarios (one "elective" and one "urgent"). The shortest waiting periods were reported consistently from the United States (from both VA and non-VA hospitals). Canada's waiting periods were more like the European waiting periods with the exception of coronary angiography for urgent cases, which more resembled the American approach. Whereas coronary angiography waiting periods were

rarely more than three months in any country, some patients in both Canada and in the United Kingdom were predicted to wait for more than nine months for "elective" cardiac surgery.

Carroll noted that information is lacking about the medical consequences of prolonged waits and their effects on key areas, such as morbidity, mortality and quality of life·. Causes of waiting times for procedures are certainly multifactorial. These include availability of hospital services, such as catheterization laboratories and operating rooms, as well as physicians' perception of the medical necessity of the procedure itself.

Literature regarding waiting lists and their implications is scarce. Naylor's (25) paper entitled "A different view of queues in Ontario" describes the multifaceted nature of the waiting list issue. Recognizing the limitations of available data, he suggested that "the experience of persons waiting for a health service can and should be studied, analyzed and summarized, as is done for any disease."

6.4 RECOMMENDATIONS

6.4.1 Resource availability and physician numbers are strongly linked to utilization and the length of waiting lists. This fact should be carefully considered in strategic health care resource planning and training program policy development, particularly for the increase in physician and resource demand predicted over the next 15 years, based on projected population ageing and physician retirement patterns.

Grade: Consensus

6.4.2 The challenge of resource availability in the diagnosis and treatment of coronary artery disease is international in scope. The Canadian Cardiovascular Society should take a leadership position in encouraging a meaningful international exchange of data and ideas on resource availability.

Grade: Consensus

6.4.3 Wide variability in utilization rates despite similar coronary artery disease prevalence rates is a regional, national and international fact. The 'right' approach is not obvious, but in the midst of this variability there is an opportunity to learn and move towards a higher and more uniform level of procedural appropriateness. This process would be assisted by the regional and national observational database proposed by this consensus report.

Grade: Consensus

REFERENCES

1. Collins-Nakai RL, Huysmans HA, Scully HE. Task Force 5: Access to cardiovascular care: an international comparison. J Am Coll Cardiol 1992;19:1477-85.
2. Meyer BJ, Meier B, Bonzel T, et al, Working Group on Coronary Circulation of the European Society of Cardiology. Working group report: interventional cardiology in Europe 1993. Eur Heart J 1996;17:1318-28.
3. Pilote L, Califf RM, Sapp S, et al. Regional variation across the United States in the management of acute myocardial infarction. N Engl J Med 1995;333:565-72.
4. Guadagnoli E, Hauptman PJ, Ayanian JZ, Pashos CL, McNeil BJ, Cleary PD. Variation in the use of cardiac procedures after acute myocardial infarction. N Engl J Med 1995;333:573-8.
5. Carroll RJ, Horn SD, Soderfeldt B, James BC, Malmberg L. International comparison of waiting times for selected cardiovascular procedures. J Am Coll Cardiol 1995;25:557-63.
6. Rouleau JL, Moye LA, Pfeffer MA, et al. A comparison of management patterns after acute myocardial infarction in Canada and the United States. N Engl J Med 1993;328:779-84.
7. Langa KM, Sussman EJ. The effect of cost-containment policies on rates of coronary revascularization in california. N Engl J Med 1993;329:1784-9.
8. Higginson LAJ, Cairns JA, Smith ER. Rates of cardiac catheterization, coronary angioplasty and coronary artery bypass surgery in Canada (1991). Can J Cardiol 1994;10:728-32.
9. Anderson GM, Grumbach K, Luft HS, Roos LL, Mustard C, Brook RH. Use of coronary artery bypass surgery in the United States and Canada; influenc of age and income. JAMA 1993;269:1661-6.
10. Roos LL, Sharp SM. Innovation, centralization and growth: coronary artery bypass graft surgery in Manitoba. Med Care 1989;27:441-52.

11. Platt GH, Svenson LW, Woodhead SE. Coronary artery bypass grafting in Alberta from 1984 to 1989. Can J Cardiol 1993;7:621-4.

12. Bernstein SJ, Hilborne LH, Leape LL, et al. The appropriateness of use of coronary angiography in New York State. JAMA 1993;269:766-9.

13. Bengtson A, Herlitz J, Karlsson T, Brandrup-Wognsen G, Hjalmarson A. The appropriateness of performing coronary angiography and coronary artery revascularizatin in a Swedish population. JAMA 1994;271:1260-5.

14. Brook RH, Park RE, Winslow CM, Kosecoff JB, Chassin MR, Hampton JR. Diagnosis and treatment of coronary artery disease: comparison of doctorsâ attitudes in the USA and the UK. Lancet 1988;i:750-3.

15. Anderson GM, Lomas J. Monitoring the diffusion of a technology: coronary artery bypass surgery in Ontario. Am J Public Health 1988;78:251-4.

16. Mark DB, Naylor CD, Hlatky MA, et al. Use of medical resources and quality of life after acute myocardial infarction in Canada and the United States. N Engl J Med 1994;331:1130-5.

17. McGlynn EA, Naylor CD, Anderson GM, et al. Comparison of the appropriateness of coronary angiography and coronary artery bypass graft surgery between Canada and New York State. JAMA 1994;272:934-40.

18. Roos LL, Bond R, Naylor CD, Chassin MR, Morris AL. Coronary angiography and bypass surgery in Manitoba and the United States: a first comparison. Can J Cardiol 1994;10:49-56.

19. Hilborne LH, Leape LL, Bernstein SJ, et al. The appropriateness of use of percutaneous transluminal coronary angioplasty in New York State. JAMA 1993;269:761-5.

20. Leape LL, Hilborne LH, Park RE, et al. The appropriateness of use of coronary artery bypass graft surgery in New York State. JAMA 1993;269:753-60.

21. Chassin MR, Kosecoff J, Park RE, et al. Does inappropriate use explain geographic variations in the use of health care services? A study of three procedures. JAMA 1987;258:2533-7.

22. Leape LL, Park RE, Solomon DH, et al. Does inappropriate use explain small-area variations in the use of health care services? JAMA 1990;263:669-72.

23. Brook RH, Park RE, Winslow CM, et al. Diagnosis and treatment of coronary diseaase: comparison of doctors attitudes in the USA and the UK. Lancet 1988;i:750-3.

24. Higginson LAJ, Cairns JA, Keon WJ, Smith ER. Rates of cardiac catheterization, coronary angioplasty and open-heart surgery in adults in Canada. Can Med Assoc J 1992;146:921-5.

25. Naylor CD. A different view of queues in Ontario. Health Aff (Millwood) 1991;10:110-28.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 7: Revascularization in Canada: Manpower and resource issues

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An inventory of human and material resources is an important part of this consensus conference mandate. This inventory process was accomplished by telephone contacts with cardiac catheterization laboratory and surgical program directors across the country. Data were requested on the numbers of procedures performed, the number of physicians performing these procedures and the number of procedure rooms in each institution. To address the issue of future personnel needs due to retirement, we obtained the ages of interventional cardiologists and surgeons. Finally, we created age and sex profiles of patients referred for surgery and angioplasty in Canada with the assistance of five cardiac centres from coast to coast. With these data and projected population ageing profiles from Statistics Canada, growth in resource demands has been projected to the year 2010, a short 13 years away. The data are sobering: personnel and resource demands of crisis proportions can be expected if coronary disease prevalence and revascularization expectations of society do not change.

We believe these data to be reliable. However, inconsistencies with information in other databases were noted. Table 7.1 indicates the number of cardiologists and cardiovascular surgeons on record in two sources other than this telephone survey. In cardiac surgery, we have confidence that our data are complete, and in fact our number is quite close to the National Specialty Society Physician Review data from 1993 (The National Specialty Physician Review is a joint project of the Canadian Medical Association [CMA], The Royal College of

Physicians and Surgeons of Canada, and the National Specialty Society). The disparity with the CMA data likely arises from the CMA looking at cardiovascular and thoracic (CVT) certificates of the Royal College, and making the incorrect assumption that all of these people are doing cardiac surgery. Those with CVT certificates also perform vascular and thoracic surgery, particularly in small centres. The larger disparity in the numbers of cardiologists reflects our point of sampling. Only cardiovascular centres with known cardiac catheterization facilities were contacted, leaving out all community-based cardiologists without admitting privileges to the centres contacted. We believe that our data on the numbers and ages of practicing interventional and catheterizing cardiologists are accurate.

7.1 CARDIOLOGY MANPOWER

Information on the number of catheterizing and interventional cardiologists and the numbers of procedures performed was obtained by direct telephone contact with catheterization laboratory directors. We acknowledge the assistance of the Quebec Heart Association in obtaining the relevant Quebec data. Prince Edward Island does not have a catheterization laboratory; their population is combined with that of Nova Scotia, their primary referral centre.

7.1.1 Catheterization laboratories and invasive cardiologists

Table 7.2 lists the numbers of catheterizing and interventional cardiologists for each province with calculations as to their numbers per 100,000 population. The numbers of catheterization laboratories in each province are also given. Catheterizing cardiologist numbers per 100,000 population average 0.97 and vary from a low of 0.37 in Manitoba to a high of 1.23 in Newfoundland. Alberta, Quebec and British Columbia are the other provinces that exceed the national average at 1.11, 1.07 and 1.03, respectively. The numbers of interventional cardiologist per 100,000 population average 0.47 and vary from a low of 0.4, again in Manitoba, to a high of 0.7 in Newfoundland, followed closely by Quebec at 0.64. Finally, there is an average of 0.23 catheterization laboratories/100,000 population in Canada, varying from 0.17 in Ontario to a high of 0.30 in Quebec, with Nova Scotia, Alberta and British Columbia close behind.

TABLE 7.1

Total Canadian cardiology manpower discrepancies in various records

	Cardiology	Adult cardiac surgery
1995: By telephone contact with program directors	457+	136
1993: By national specialty society physician review	687	124
1995: Number by CMA masterfile database	736	269

CMA Canadian Medical Association

7.1.2 Ages of cardiologists

There are 265 catheterizing cardiologists in Canada. Assuming that all 265 continue to practise until they are 65 years old, 30% or 80 new cardiologists skilled in cardiac catheterization will be needed by the year 2010. The need is similar across the country, but Quebec has a younger group of catheterizing cardiologists with only 22% expected to retire in the next 15 years.

An important part of the manpower equation is the rate at which Canadian interventional cardiologists, cardiovascular surgeons and graduates of cardiology and cardiovascular surgery programs emigrate to the United States or other countries (data are being collected on this issue, but are not yet ready for publication).

7.1.3 Cardiology training programs

There are 15 cardiology training programs in Canada: one each in British Columbia, Saskatchewan, Manitoba and Nova Scotia, two in Alberta, four in Quebec and five in Ontario. In these training programs there are 58 fellows: 51 Canadians and seven foreign fellows who plan to return to their homeland upon completion of training. An estimated 15 to 20 Canadian fellows/year are expected to complete their training for the next five years.

There are two important developments with respect to cardiology training. First, due to restricted government funding and a trend across the country to increase the numbers of general medicine residents at the expense of subspecialty programs, a decrease in the number of cardiology fellows is planned for all training programs in Canada. Second, the adoption of a three-year cardiology program will impose a one-year delay in the schedule of resident completions. With these restrictions, the ongoing problem of physician emigration and retirement patterns expected over the next decade, significant manpower problems can be expected.

TABLE 7.2

Numbers of catheterizing and interventional adult cardiologists and catheterization laboratories per 100,000 population in Canada by province

Province	Population (1991)	Number of catheterizing cardiologists	Catheterizing cardiologists/ 100,000 population	Number of interventional cardiologists	Interventional cardiologists/ 100,000 population	Number of catheterization laboratories	Catheterization laboratories/ 100,000 population
British Columbia	3,309,858	34	1.03	15	0.45	9	0.27
Alberta	2,603,202	29	1.11	14	0.54	7	0.27
Saskatchewan	988,928	8	0.81	4	0.40	2	0.20
Manitoba	1,091,942	4	0.37	3	0.27	2	0.18
Ontario	10,084,885	98	0.97	37	0.37	17	0.17
Quebec	6,895,963	74	1.07	44	0.64	21	0.30
New Brunswick	723,900	3	0.41	3	0.41	2	0.28
Nova Scotia and Prince Edward Island	1,029,707*	8	0.77	5	0.49	3	0.29
Newfoundland	568,474	7	1.23	4	0.70	1	0.18
Canada	27,296,859	265	0.97	129	0.47	64	0.23

**One-third of Prince Edward Island's cases are done in New Brunswick (personal communication)*

TABLE 7.3

Numbers of Canadian catheterizing cardiologists by province and cardiologist age group

Province	Number	Age (years)				
		30-39	40-49	50-59	60-64	Ò65
British Columbia	34	4	16	11	3	0
Alberta	29	8	11	6	2	2
Saskatchewan	8	1	4	2	0	1
Manitoba	4	1	1	0	2	0
Ontario	98	31	36	23	6	2
Quebec	74	29	27	15	2	1
New Brunswick	3	1	1	1	0	0
Nova Scotia	8	4	3	0	1	0
Newfoundland	7	4	2	1	0	0
Total	265	83 (31%)	101 (38%)	59 (22%)	16 (6%)	6 (2%)

7.2 SURGICAL MANPOWER

Data on the numbers of surgical units and surgeons in each province per 100,000 population, the ages of practicing surgeons and the numbers of cases they do each year, on average, were obtained by direct telephone contact with the surgical department heads.

7.2.1 Surgical units and surgeons

There are 136 practicing cardiovascular surgeons in Canada, an average of 0.5/100,000 population. Interprovincial variability extends from a low of 0.35 in Newfoundland to a high of 0.61 in Quebec, but the overall range is narrow. Canadian CVT surgeons spend a variable amount of their time performing cardiac surgery. The remainder of their time is spent on thoracic and vascular surgery, teaching and research. As cardiac surgery demand increases, surgeons may choose to spend more of their time on cardiac surgery and less on other procedures, but the shift will seldom be complete, particularly in academic centres. One secondary reviewer has suggested that all CVT surgeons be resurveyed. In this

communication they would be asked to specify the percentage of their time they spend performing cardiac surgery. The resulting numbers, expressed as Îfulltime equivalents', then would be included in the tables as complementary data reflecting the potential reserve in the surgical manpower base as we contemplate retirement patterns and population growth. This appears to be an excellent suggestion, and will be acted on as time and resources permit.

TABLE 7.4

Number of cardiac surgeons and surgical units in Canada by province per 100,000 population

Province	Population (1991)	Number of surgeons	Surgeons/100,000 population	Number of surgical units	Units/100,000 population
British Columbia	3,309,858	16	0.48	4	0.12
Alberta	2,603,202	11	0.42	3	0.12
Saskatchewan	988,928	5	0.51	2	0.20
Manitoba	1,091,942	6	0.55	2	0.18
Ontario	10,084,885	46	0.46	9	0.09
Quebec	6,895,963	42	0.61	12	0.17
New Brunswick	723,900	3	0.41	1	0.14
Nova Scotia and Prince Edward Is.	1,029,707	5	0.48	1	0.10
Newfoundland	568,474	2	0.35	1	0.18
Canada	27,296,859	136	0.50	35	0.13

TABLE 7.5

Adult open heart surgery units in Canada

Province	City	Hospital
British Columbia	New Westminster	Royal Columbian Hospital
	Vancouver	St Paul's Hospital, Vancouver General Hospital
	Victoria	Royal Jubilee Hospital
Alberta	Calgary	Foothills Provincial General Hospital, Holy Cross Hospital
	Edmonton	University of Alberta Hospitals
Saskatchewan	Regina	Plains Health Centre
	Saskatoon	Royal University Hospital
Manitoba	Winnipeg	Health Sciences Centre, St Boniface General Hospital
Ontario	Hamilton	Hamilton Health Sciences Corp - General Site
	Kingston	Kingston General Hospital
	London	London Health Sciences Centre - University Campus Site and Victoria Campus Site
	Ottawa	Ottawa Heart Institute
	Sudbury	Sudbury Memorial Hospital
	Toronto	St Michael's Hospital, Sunnybrook Health Science Centre, Toronto Hospital
Quebec	Chicoutimi	L'Hôpital de Chicoutimi
	-	Centre Hospitalier de l'Université de Montréal - Pavillon Nôtre-Dame, Hôpital du Sacré-Coeur de Montréal, Hôpital St-Luc, Hôpital Ste-Justine, Hôtel-Dieu de Montréal, Institut de Cardiologie de Montréal, - General Hospital, Royal Victoria Hospital, Sir Mortimer B Davis Jewish General Hospital
	Quebec	L'Hôtel-Dieu de Québec
	Ste-Foy	L'Hôpital Laval
	Sherbrooke	Centre l'université de santé de l'Estrie
New Brunswick	Saint John	Saint John Regional Hospital
Nova Scotia	Halifax	Queen Elizabeth II Health Sciences Centre
Newfoundland	St John's	Health Sciences Centre

The number of surgical units per 100,000 population averages 0.13 and varies from 0.09 in Ontario to a high of 0.18 in Manitoba and Newfoundland, with Quebec at 0.17.

All adult cardiovascular surgery centres are listed in Table 7.5.

7.2.2 Ages of surgeons

The expected retirement pattern for surgeons is different from that described for catheterizing cardiologists. By the year 2010, 46%, or 62 of the country's 136 adult cardiac surgeons, will have reached the age of 65 years, and because cardiac surgeons do not all continue to practise until this age, the demand for adult cardiac surgeons over the next 15 years will be substantial (Table 7.6).

7.2.3 Numbers of procedures per surgeon

Table 7.7 describes the caseload of adult cardiac surgeons by province. The average annual caseload of open-heart cases is 157 per surgeon (as of this writing, data from Ontario and Quebec are not available). Within the reporting provinces, the lowest caseload was 122 in Manitoba; Nova Scotia and Newfoundland were the highest at 189 and 190, respectively.

7.2.4 Surgical training programs

There are eight active cardiac surgery training programs in Canada: one each in British Columbia and Alberta, four in Ontario and two in Quebec. There are 24 residents in training, 16 Canadian and eight foreign. The expected number of residents completing their training over the next five years is shown in Table 2.8.

7.3 FUTURE RESOURCE DEMANDS

Future revascularization resource requirements will be determined by

- the changing age distribution profile of the population;
- changing technology, including the development of new noninterventional strategies in coronary disease treatment;

TABLE 7.6

Numbers of adult cardiac surgeons in Canada by province and surgeon age group

Province	Number	Age (years)				
		30-39	40-49	50-59	60-64	Ò65
British Columbia	16	1	6	6	3	0
Alberta	11	2	7	1	1	0
Saskatchewan	5	0	4	1	0	0
Manitoba	6	1	1	2	1	1
Ontario	46	11	14	14	4	3
Quebec	42	7	15	14	3	3
New Brunswick	3	1	1	1	0	0
Nova Scotia	5	0	2	1	2	0
Newfoundland	2	0	0	2	0	0
Canada	136	23 (17%)	50 (37%)	42 (31%)	14 (10%)	7 (5%)

TABLE 7.7

Average number of adult open-heart operations performed per surgeon in Canada in each province in 1994

Province	Number of surgeons	Number of open-heart operations (1994)	Open-heart operations per surgeon
British Columbia	16	2544	159
Alberta	11	1666	151
Saskatchewan	5	727	145
Manitoba	6	734	122
Ontario	46		
Quebec	42		
New Brunswick	3	541	180
Nova Scotia	5	943	189
Newfoundland	2	379	190
Canada	136		

TABLE 7.8

Numbers of cardiac surgical residents expected to complete training by 2000

Year	Canadian	Foreign
1995	6	3
1996	4	3
1997	4	2
1998	2	0

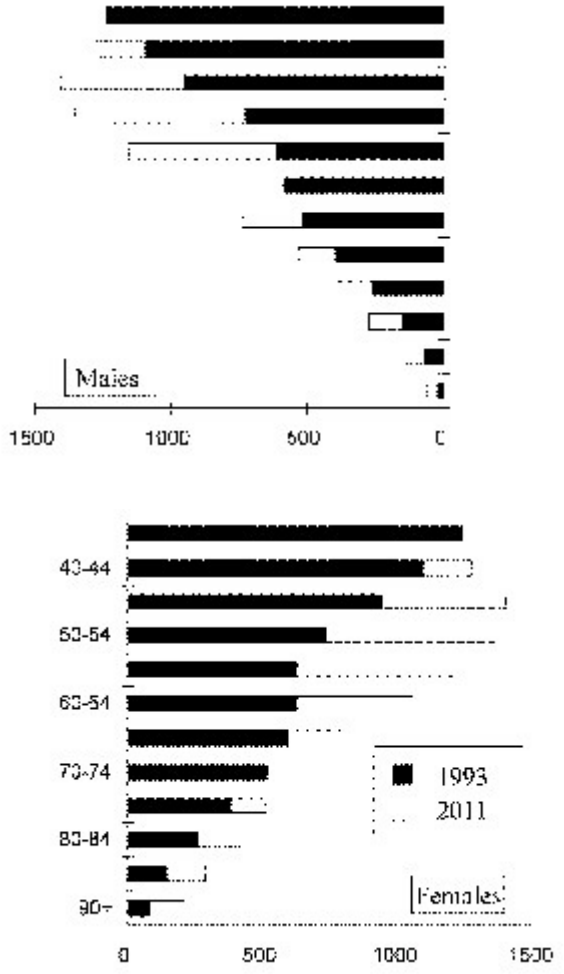
- retirement patterns of existing surgeons and interventional cardiologists; and
- changes in the prevalence of coronary artery disease.

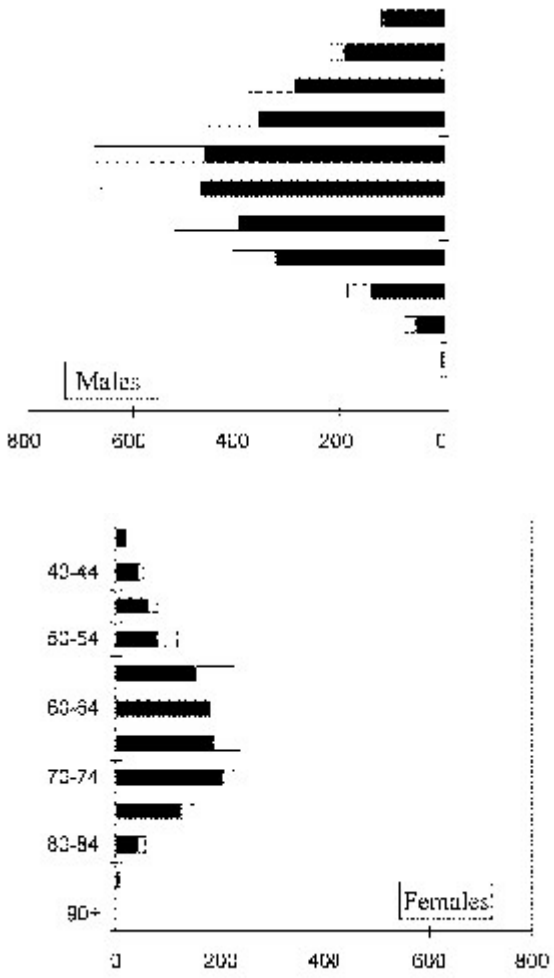
Although we hope that this is not the case, it does not seem likely that there will be a substantial change in age-adjusted coronary artery disease prevalence over the next 10 to 15 years. In the clinical Chapters 2 through 4, the authors speculate on the impact of changing technology and changing pathophysiological understanding of the various coronary disease syndromes on the question of future resource demand. These opinions are summarized below. Data are presented on expected retirement rates of physicians earlier in this chapter. Finally, data are presented on the possible influence of population ageing patterns on resource requirements.

7.3.1 Impact of population ageing

In Figure 7.1, the actual age and sex distribution of the Canadian population is shown as black bars for the year 1993. The source of this information is the Census Division of Statistics Canada. Also included is a projection of the population in the year 2011 (white bars). With current trends in population ageing, the age groups expected to receive the greatest relative increase in numbers is the 45 to 70 year age range, the age in which coronary disease prevalence is the highest.

Records from cardiac clinical research units in Halifax, Toronto, Calgary and Vancouver were reviewed for the year 1993, and a similar diagram was constructed showing the age and sex distribution of coronary artery angioplasty patients. This distribution is shown as black bars in Figure 7.2. By using the population growth projections from Figure 7.1, an age and sex population profile was calculated for the year 2011 for the angioplasty population. It was assumed that disease prevalence will stay the same and that there will be no substantial changes in the indications for this procedure over this time. Based on this analysis, the number of angioplasties projected for the year 2011 is 34% greater than the current volume based on expected population changes alone.





Similarly, the 1993 surgery population was portrayed in an age and sex distribution profile, shown in Figure 7.3 along with the growth expectations for the year 2011. Based on this analysis, the surgical population will increase by 36%, assuming no change in treatment strategies and no change in disease prevalence.

7.3.2 Impact of changing technology

The past decade has witnessed an explosive and unprecedented growth in angioplasty procedures (one million procedures were performed worldwide this year). With this growth there have been significant increases in bypass surgery as well. Given this history, attempts to predict resource requirements over the next decade, because of changes in technology and pharmacotherapy, are hazardous.

A major deterrent to increasing use of angioplasty in a wide variety of ischemic syndromes is the issue of restenosis. If a 'cure' for this problem is found, growth in angioplasty numbers could be explosive, with a profound impact on the need for catheterization laboratories and interventional cardiologists. The authors also see balloon and surgical technology making significant advances in the next five years that will continue the revascularization pressure. New medical options may emerge that could stabilize many patients with acute coronary syndromes, reducing the impetus to early invasive investigation, at least in some subgroups. Not all medical advances have served to reduce the need for revascularization, however. Saving patients by thrombolytic therapy will serve only to increase the number of patients with complex disease who will require intervention as their disease progresses. Hopefully, the wider application of secondary preventive measures will provide a significant force to balance this growing need for revascularization.

7.3.3 Resource needs in 2010

Without financial constraints on the process, physician retirement expectations in combination with the ageing of the population and expected improvements in technology will create a need for 135 new surgeons, 19 new surgical units, 109 new interventional cardiologists and 34 new catheterization laboratories by the year 2011. *These projections do not include manpower needs created by the pervasive trend of physician migration to the United States and other countries.* Without major shifts in priority in our society, it is unlikely that this will happen even if the assumptions are true. Clearly, a renewed effort in the area of secondary prevention is critically important, along with renewed efforts to predict those procedures most likely to achieve symptom-free survival at a reasonable cost.

7.4 RECOMMENDATIONS

7.4.1 The effect of expected changes in disease prevalence and population ageing over the next decade must be tracked by the proposed observational database.

Grade: Consensus

Population ageing trends predict a 30% increase in the number of patients requiring revascularization by 2010.

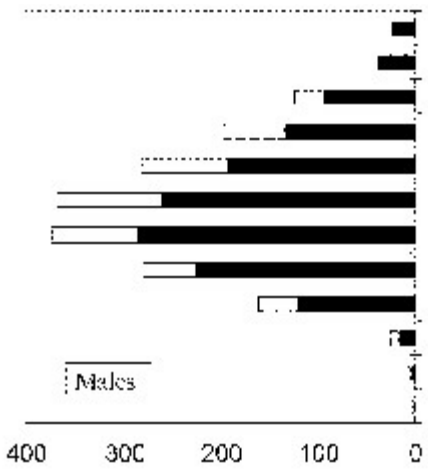
7.4.2 Training program directors should develop a plan to meet the major manpower shortage expected over the next decade.

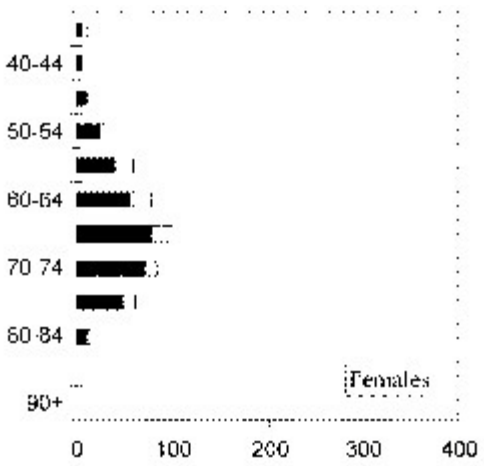
Grade: Consensus

By the year 2010 over 40% of cardiovascular surgeons and 30% of interventional cardiologists will retire. These projections exclude the impact of ongoing physician migration, early retirement and other reasons to leave active practice prematurely.

7.4.3 Additional revascularization facilities will soon be required to meet population demands. The Canadian Cardiovascular Society should develop a policy on the optimal nature and location of these additional resources.

Grade: Consensus





The rapid delivery of care for many acute coronary syndromes is now known to be crucial.

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 8: Resource allocation in coronary revascularization

Peter A Singer MD MPH FRCPC, Randi Zlotnik Shaul LLM (* Primary panel member)*

Because demand exceeds supply, coronary revascularization is a scarce resource. How should it be distributed fairly?

Resource allocation can be defined as the distribution of goods or services in a situation of resource scarcity, where not all health care expected to be beneficial is provided to all patients who might need or want it.

The nature of resource allocation decisions depends on the model of health care financing and delivery. In a private system such as that in the United States, ability to pay may be the primary determinant of access to a scarce resource. In a public system such as that in Canada, ability to pay should not be a determinant of access.

Resource allocation decisions can be implicit or explicit. It is unfair to allocate resources based on implicit criteria that may vary from physician to physician. Resource allocation criteria should be explicit, evenly applied, publicly known and open to review.

An alternative to resource allocation is to augment the availability of the scarce resource. This is, of course, not possible for every treatment in the Canadian health care system without an increase in taxes or the deficit. This chapter describes a theoretical framework for resource allocation decisions and explores the practical application of this framework to coronary revascularization.

8.1 THEORETICAL FRAMEWORK

The appropriate ethical framework from which to approach resource allocation decisions is justice. The formal principle of justice states that equals should be treated equally and unequals treated unequally. The problem with this formal principle is that it does not stipulate the respects in which people should be judged equal or unequal. Therefore, the formal principle needs to be supplemented by material principles of justice that describe these criteria.

The main material principles of justice are need (based in egalitarian theories of justice), benefit (based in utilitarian theories of justice) and fair procedures (based in libertarian theories of justice). Therefore, the following are morally justifiable criteria on which to base resource allocation decisions in revascularization for coronary artery disease:

- need or urgency;
- benefit or effectiveness; and
- fair procedures.

In resource allocation decisions discrimination occurs when decision-makers appeal to material principles that have been specifically prohibited by an appropriate authority such as the Canadian Charter of Rights and Freedoms or provincial human rights laws. The following are legally proscribed criteria on which to base resource allocation decisions in revascularization for coronary artery disease:

- sex;
- race;
- national or ethnic origin;
- colour;
- religion;
- age;
- physical or mental disability; and
- sexual orientation.

The legal proscription refers to the use of these criteria alone. For instance, in certain patients, age may be a marker for comorbidity that would lead to less benefit from coronary revascularization. Benefit, of course, is not a legally proscribed criterion.

8.2 APPLICATION TO PRACTICE

Resource allocation decisions regarding coronary revascularization are usually made at two distinct levels. The cardiovascular team usually decides which referred patients will be revascularized (and when). The provincial government usually decides how much funding will be provided for coronary revascularization (and where cardiovascular units will be located). The practical application of the theoretical framework at each of these levels is examined below.

8.2.1 Cardiovascular team decisions

The problem with applying the theoretical framework to clinical decision-making is twofold. First, the ethically and legally defensible criteria on which to base resource allocation decisions are usually not explicitly and clearly stipulated. In practical terms, what is our taxonomy of effectiveness? What is our taxonomy of need? The other chapters that comprise this consensus conference could help to clarify these questions.

Second, the relative weight of these criteria, which often conflict, is not explicitly addressed. For instance, the person who needs a revascularization procedure the most, such as someone in cardiogenic shock, is not always the one who has the highest expected survival rate or has been waiting the longest.

Unfortunately, there is no overarching theory of justice that provides for balancing the various ethical and legal criteria in a principled way. In the absence of a substantive method for balancing competing criteria, the only alternative is to use a procedural approach. The process of balancing criteria could be achieved by a national consensus committee, such as this one, and applied by Canada's cardiovascular units. Ideally, a committee designing a resource allocation scheme for revascularization would also include public representation (fair

procedures). The criteria should be communicated to the broader community, including potential patients (fair procedures).

A good example of how this could be done is the American experience in organ transplantation. Every organ transplantation is governed by the policies of the United Network for Organ Sharing (UNOS). For example, UNOS policies prioritize patients on the waiting list for liver transplantation according to the following criteria: degree of medical urgency, blood type, time waiting and donor size. Specific numbers of points are awarded for various levels in each of these categories, and the person with the most points receives the next available liver. The criteria are national in scope, but they are applied locally by transplant units. Although a United States General Accounting Office report has raised questions about how consistently UNOS criteria are applied, the UNOS approach has the advantage of producing policies that are consistent from unit to unit, explicit and open to public scrutiny.

8.2.2 Provincial government decisions

Other chapters in this consensus highlight marked regional differences in access to cardiac catheterization laboratories and procedure waiting times. Are these differences fair?

Because these differences result from provincial government decisions about funding and location of cardiovascular facilities and services, they raise constitutional questions.

The principles of section 36 of the Constitution may be used to support the recognition of province of residence as a ground warranting constitutional protection. Section 36 (1) reads:

Parliament and the legislatures, together with the Government of Canada and the provincial governments, are committed to

a. promoting equal opportunities for the well-being of Canadians;
b. furthering economic development to reduce disparities in opportunity; and
c. providing essential public services of reasonable quality to all Canadians.

Subsection 36(1)(c) works as a general reaffirmation of the principle of regional equality presented by the criteria of comprehensiveness, accessibility, universality and portability in the *Canada Health Act.*

Moreover, section 15 of the *Charter* prohibits discrimination on a number of grounds (listed under section 8.1, Theoretical framework). While place of residence is not a prohibited ground of discrimination listed in section 15, a number of courts have considered distinctions based on residence to violate the *Charter.*

Whether regional disparities in coronary revascularization services could be successfully argued to violate the *Charter* is unclear. Presumably, the differences in waiting time, for instance, would not violate section 15 if they were shown to correlate with differences in need or potential effectiveness. Even if the regional differences were shown to violate section 15, they would still not be considered unconstitutional if they were 'saved' by section 1, that is, if they can be "demonstrably justified in a free and democratic society".

Given the constitutional division of powers, with responsibility for health care a matter of provincial jurisdiction, it is unlikely that provinces would be required to have precisely identical allocation policies with respect to cardiovascular services. The Canada Health Act requires "reasonable access" to services. This suggests that each province must meet a basic minimum standard of access to cardiovascular services. If a province were to choose to exceed this basic minimum by providing superior access, thereby creating regional disparities, it would be entitled to do so. Therefore, regional disparities do not necessarily imply unconstitutional government action if all provinces meet a basic minimum.

This, of course, raises the question of what is the basic minimum standard for access to coronary revascularization. This would likely take into account population needs and geographical dispersion. The Canadian Cardiovascular Society consensus committee could address this question in its recommendations.

8.3 RECOMMENDATIONS

The challenge for allocation policies in coronary revascularization is to move back and forth between the theoretical ethical and legal structures, and the practical realities. This chapter has only begun to build the necessary bridges. To begin this process, the following recommendations are submitted:

8.3.1 Resource allocation decisions regarding coronary revascularization should be made on the basis of need or urgency; benefit or effectiveness; and fair procedures.

Grade: Consensus

8.3.2 Resource allocation decisions regarding coronary revascularization should not be made on the basis of age alone or other constitutionally prohibited grounds.

Grade: Consensus

8.3.3 Canadian cardiovascular units should develop explicit guidelines for access to coronary revascularization.

Grade: Consensus

8.3.4 Provinces should meet a basic minimum standard for access to coronary revascularization. Variation in waiting times across provinces would be tolerable if each met the basic minimum standard for access. This standard has yet to be defined, and the Canadian Cardiovascular Society should lead the effort.

Grade: Consensus

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INDICATIONS FOR AND ACCESS TO REVASCULARIZATION

Chapter 9: Waiting list issues

Merril L Knudtson MD FRCPC

As long as procedure demand exceeds fiscal, personnel or facility resources, waiting lists will be inevitable. In fact, it has been argued that a waiting list of modest size is a sign of prudent application of limited resources (1-3). As the size of the waiting list grows, however, an explicit management policy is critical to ensure fair access to these limited resources and to optimize symptom-free survival (4). Despite prior agreement on general waiting list principles, panels of coronary artery disease 'experts' have been shown to agree only infrequently on waiting list priority assessment when presented with a series of test cases (5). Despite this, the consensus members believe that intelligent priority decisions can be made. In this chapter, factors that influence priority decisions are presented and basic waiting list principles are proposed.

When a decision to revascularize has been appropriately made, any delay could potentially limit the symptom or survival benefit to be expected from revascularization. With waiting there is risk of death, but beyond risk there is the reality of being exposed to unacceptable symptoms and the frequent need to have patients place their lives 'on hold' while waiting for their number to be called. The purpose of a waiting list management plan is not only to ensure that the risk of death is fairly distributed. Pain and suffering and psychosocial stress incurred while on the queue must also be considered.

A national database is proposed in this report. Data on regional waiting times and events while on the queue will allow the establishment of national waiting list benchmarks and a more

credible basis for queue priority and acceptable waiting time decisions. Finally, data so gathered will help predict resource needs for the investigation and treatment of coronary artery disease.

9.1 CARDIAC CATHETERIZATION - A GATEKEEPER?

The *decision to perform* an angiogram is an integral part of eventual revascularization decision-making. In this sense, coronary angiography is a 'gatekeeper' in the process of revascularization. It is the majority consensus opinion that inappropriate angiographic decisions could play a role in creating unacceptable revascularization queue lengths. Without appropriate pretest discussion and scrutiny, angiography can initiate an interventional momentum that may be as inappropriate as it is hard to restrain.

On the other hand, the Canadian and international utilization statistics presented in Chapters 5 and 6 show no strong correlation between catheterization rates and the rate of subsequent revascularization. A swing away from the use of angiography would likely increase the demand for noninvasive testing facilities, and delays at the noninvasive testing level again may create lost opportunity for benefit. Undue reticence in performing an angiogram where indicated could contribute to reduced survival and symptom benefits. Also, disproving the diagnosis of significant coronary disease and assessing prognosis are often significant motivations for coronary angiography even though revascularization is not contemplated.

The proposed national observational database will monitor cardiac catheterization as well as revascularization. Among the goals of this database will be a reduction in the number of inappropriate diagnostic and interventional procedures. The process will also allow identification of instances where interventions were inappropriately withheld.

9.2 WAITING LIST DETERMINANTS

Factors governing priority assignment in the cardiac surgery queue have included the concept of *vital risk,* or the absolute mortality risk of delaying surgery (6); and allowable waiting times

derived by a consensus of 'experts'. In addition we feel that the ethical principles discussed in Chapter 8 are relevant to the waiting list process and specific comments on the ethics of waiting lists are included. Finally, effectiveness data obtained from the recommended national observational database would be an important resource in the process of queue assignment.

9.2.1 Vital risk

The identification of patients whose symptom-free survival can be improved by revascularization is a major motivation for coronary angiography. After angiography, the potential for a survival benefit is determined primarily by assessment of coronary anatomy and ventricular function, with appropriate regard to the risk of the procedures that are to be used to achieve this survival benefit.

Where a mortality benefit of an intervention over medical therapy is expected, **any procedural delay risks reducing the potential survival benefit**. As the magnitude of the survival benefit over medical therapy increases, so does the risk of waiting. Waiting list prioritization must reflect this relative risk of waiting. In this section, relevant aspects of disease and treatment mortality are discussed.

Application of randomized clinical trial data to quantify the mortality benefit of an intervention in a specific case has important limitations. The highly selective nature of prerandomization screening in randomized trials frequently results in selection of only a small fraction of the typical population to which the therapy eventually will be applied. The actual benefit to a specific patient may be greater or less than the benefit observed in the relevant clinical trials, depending on many factors (7). In most clinical trials, severely symptomatic patients were excluded from randomization. Because of these exclusions, it is uncertain whether there is an independent contribution of symptom level to mortality. Nonrandomized data from the CASS (Coronary Artery Surgery Study) Registry, however, suggest that severe symptoms do contribute to the mortality benefit of surgery (8,9).

What is the monthly increase in mortality that a patient faces by delaying treatment? If greater survival is to be expected from an intervention, an estimate of the risk taken by delaying this

treatment can be derived from the rate of separation of the intervention and nonintervention survival curves published after randomized clinical trials. The assumption is that there is no clinical reason to delay the procedure to improve surgical risk. In the analyses that follow, the survival curve separation rates are presented as an incremental monthly mortality rate that patients face by virtue of being in a queue. These estimates do not take into account additional risk that may be imposed by other clinical status and lesion morphology considerations specifically excluded from the randomized trials. This analysis should be interpreted with caution *because it is only* ***an indicator of relative risk*** *and may not be accurate in absolute terms when applied to specific patients.* The factors that determine these separation rates for patients with stable and unstable angina are discussed separately in the next two sections. Rachlis et al (6) published an extension of this approach, including adjustments for left ventricular (LV) function and symptom severity.

9.2.1.1 Stable angina pectoris: Survival of patients with LV dysfunction and double vessel disease, particularly patients with proximal left anterior descending (LAD) coronary artery disease, can be improved with surgery. Randomized clinical trials in this patient group show a two-year delay before surgical and medical survival curves separate, so there may be no reduction in the mortality benefit expected with a moderate delay in treatment (10,11). If this is true, the revascularization pressure with this type of disease should be driven more by symptoms and lesion morphology considerations than by the need to act quickly to preserve a mortality advantage. It may be, however, that this survival curve separation delay represents a latency of benefit from early surgical intervention and that delays in treatment do increase mortality (5). The model presented assumes that there is no loss of mortality benefit by delaying intervention based on extent of disease alone in patients with double vessel disease involving the proximal LAD.

In triple vessel and left main disease, surgical and medical survival curve separation begins immediately. The mortality impact of treatment delay is summarized in Table 9.1. Also shown is a *relative allowed waiting time* index that allows fair risk distribution between groups. Other things being equal, for example, a patient with triple vessel disease who waited three to five weeks would be exposed to approximately the same additional risk as a patient with left main disease who waited one week.

This table is derived from the *highly selected patient subgroups* included in the randomized trials specified. ***At best the numbers are of value as a relative index of waiting risk.*** In absolute terms, the numbers probably underestimate the true risk of waiting. In individual cases the risk of an intervention delay may be significantly higher or lower when lesion morphology, myocardium at risk and other factors are considered. Severely symptomatic patients were excluded from most randomized trials, for example. To avoid the implication that exercise test data can be used independently to change the relative risk position of one of these groups with respect to another, exercise data are not included in the table. Studies have shown, however, that the presence of *a strongly positive treadmill exercise test, or large anterior or multiple ischemic abnormalities on nuclear scintigraphy* are independent predictors of a poor outcome and hence reasonably predict a surgical benefit over medical therapy. There may be an expected additional monthly mortality while waiting of 0.9% when all patients with these noninvasive test features are assessed (12). No data are available on the degree to which the surgical benefit of a patient with triple vessel disease, poor LV function and a strongly positive exercise test compares with that of a patient with left main disease and an exercise test that is not strongly positive, for example.

TABLE 9.1

Monthly vital risk of delaying surgery in patient subgroups with stable angina pectoris (from randomized trial data)

Subgroup	Additional monthly mortality while waiting (%)	Relative waiting times with equal additional risk(arbitrary units)	Reference
Left main coronary artery	0.7 to 1.5	1	11,31
3VD + poor LV	0.4	2-3	10
3VD	0.25 to 0.5	3-5	10,11
Poor LV alone	0.2	5-7	10

3VD Three vessel disease; LV Left ventricular function

Within the groups listed in the table, there is risk variability depending on lesion severity as well. The risk in a patient with a 70% smooth left main lesion, for example, is expected to be substantially less than with a 90% left main lesion. The risk of coronary artery disease progression is known to increase with lesion severity as well as with certain morphological features (13). It should be pointed out, however, that less severe and pliable lesions of even less than 50% luminal diameter reduction are vulnerable to unexpected rupture with catastrophic results.

For patients with single vessel disease, and those with double vessel disease without proximal LAD involvement or LV dysfunction, there is no apparent mortality advantage to intervention. With bypass surgery, in fact, most randomized trials suggest that there may be a mortality *disadvantage* with intervention compared with medical therapy. Traditionally in these patient subsets, however, the goal of intervention is not mortality reduction, but symptom control. With the possibility of a surgical mortality disadvantage, the advocates of intervention in an individual case must be convinced that the level of symptoms and the intensity of medical therapy justify this approach. A real challenge continues in assigning relative surgical queue positions to patients with severe symptoms without an expected mortality advantage, versus those who are less symptomatic but with an expected mortality advantage.

For patients with *silent ischemia,* the mortality advantage that may be presented by surgical intervention is likely equivalent to that of patients with stable angina and similar anatomy. Clearly the presence of silent ischemia is an independent factor for poor outcome that is incremental to symptoms and even coronary anatomy. Waiting list priority assignments of patients with silent ischemia consider factors such as the presence of a strongly positive exercise test, or an extensive anterior or multiple separate ischemic regions identified on noninvasive testing, in addition to anatomy and LV function.

Relative mortality benefit is also determined by the amount of myocardium in jeopardy by lesions present and vulnerability to acute change. Although designations of 'single, 'double' and 'triple' vessel disease have been used in most clinical trials to facilitate data analysis,

careful assessment of the angiogram of each patient on the waiting list is needed to compare the amount of myocardium at risk. A patient with a proximal LAD lesion and a lesion in a diminutive circumflex artery, for example, would deserve a lower queue position than a patient with proximal LAD disease and a lesion in a large circumflex system, although both have double vessel - LAD and circumflex - disease. Also anatomical vulnerability is an important issue. A patient with two occluded vessels that receive good collateral support likely has a low risk of acute coronary events during a surgical wait. On the other hand, a patient with two diseased vessels that are patent and do not receive collateral support may be at considerable risk.

9.2.1.2 Unstable angina pectoris In randomized trials of surgery and medical therapy in unstable angina, the presence of LV dysfunction and triple vessel disease again is associated with improved survival with surgery (1,14-16). Although not confirmed by the National Cooperative Study Group, several investigators, in particular the Veterans Administration Study Group, reported an important surgical survival advantage in unstable angina patients who exhibit reversible electrocardiographic (ECG) changes (2,14). Although supporting the utility of ECG changes in the diagnostic accuracy of unstable angina, the *Quick Reference Guide for Clinicians* of Braunwald et al (17) does not give the presence of ECG changes an independent role in revascularization decision-making. A recent report from Rizik et al (18), evaluating a prospectively applied grading system for unstable angina patients, found that ECG changes were associated with in-hospital infarction, death and intractable angina.

Unstable angina trials had a number of important exclusion criteria. These exclusion criteria include recent infarction (15,19-21), ejection fraction less than 0.30 and left main disease (1,4,20,22), elderly patients (1,20,23) and previous bypass surgery (15). It is likely that these factors should play a role in priority decisions on revascularization waiting lists for patients with unstable angina, but their individual importance is not clear. Patients with left main disease and unstable angina presumably would enjoy a mortality benefit even greater than that seen with triple vessel disease and unstable angina, as was the case in the stable angina trials.

Unstable angina is the most common indication for cardiac catheterization and for admission to acute care cardiac facilities. A policy of medical stabilization can usually be followed with deferred revascularization based on coronary anatomy, ventricular function and the response to medical therapy (17,20,23,24). It is also clear, however, that the eventual crossover to surgery is high when medical therapy is assigned in most unstable angina trials, but there appears to be no mortality disadvantage in the crossover process.

9.2.2 Allowable waiting times based on expert opinion

In the absence of more objective data defining what is an acceptable waiting period for bypass surgery, Naylor and colleagues (5,25) undertook a consensus process aimed at synthesizing the opinion of cardiac experts in Ontario on this issue. A series of case scenarios, including all suspected variables that clinicians were felt to use in defining revascularization urgency, were prepared, and opinions were sought as to allowable waiting times for each scenario. Seven levels of urgency were defined with preset, acceptable time limit definitions for each level, as indicated in Table 9.2.

TABLE 9.2

Levels of urgency determining allowable waiting time for bypass surgery

Level	Allowed waiting time
1	Immediate
2	<24 h
3	24-72 h
4	3-14 days
5	2-6 weeks
6	6 weeks to 3 months
7	3-6 months

Factors felt to be important in selecting the most appropriate level are listed below.

- **Symptom status.** By prior agreement, participants in the consensus process had decided that "the dominant urgency determinant should be symptom status". A modified Canadian Cardiovascular Society (CCS) classification of symptoms was used. Level scores of 2 and 3 were reserved for CCS IV-C patients with "symptoms not manageable on oral therapy, requiring coronary care monitoring and parenteral medications (generally interpreted as meaning intravenous nitroglycerine)". CCS IV-B patients with "symptoms improved but angina with minimal provocation" received ratings of 3 and 4, requiring continued hospitalization. CCS I to III stable angina and unstable angina IV-B patients (controlled symptoms on medications) received level scores of 5 to 7.
- Angiographic coronary artery severity. Within the level ranges given above, priority is assigned according to five angiographic categories of decreasing queue priority. Special priority is given to patients with disease in the proximal LAD segment. The categories are (a) left main; (b) double or triple vessel disease with proximal LAD involvement; (c) triple vessel disease without proximal LAD involvement; (d) single vessel proximal LAD disease; and (e) other single and double vessel disease.
- Noninvasive test data. Where test data are available, the presence of large anterior or multiple region perfusion defects would result in a level modification of between 0.75 and 0.9. (In practice, precautions are usually taken to ensure that patients who are felt to be too sick to be subjected to noninvasive testing are not penalized.)
- LV function. In the above level assignments, patients are assumed to have grade II ventricles. The treatment level of patients with grade III and IV ventricles is adjusted down by 0.2 and, curiously, those with grade I ventricles are adjusted up by a similar amount.

Although one may criticize aspects of this process and the assumptions made, this important work has at least established a reasonable starting point in the process of queue priority assignment. The onus is clearly on those who criticize the process to offer and justify an alternative approach.

However, the strong symptom orientation of the panel-of-experts approach creates important operational flaws. Parenteral nitroglycerine therapy (CCS class IV-C) leads to a one- to three-day wait, while incompletely controlled symptoms (CCS class IV-B) on long acting nitrates leads to a wait of up to two weeks or longer. It is difficult not to be influenced by these large differences in waiting times when deciding to institute or discontinue intravenous nitroglycerine therapy. The distinction between CCS class IV-A and IV-B is particularly difficult in the hospital environment where activity is restricted. The assumption is usually made that in the hospital, but out of the coronary care unit, a patient presenting initially with an unstable coronary syndrome has CCS class IV-B symptoms as long as he or she remains an in-patient. The increase in waiting time that would result if this patient were discharged and subsequently discovered to have controlled symptoms could range from six weeks to six months, depending on anatomy. The onus is on cardiovascular centres using the consensus approach to ensure that solutions are found to these potential problems.

9.2.3 Ethical considerations

With the serious shortcomings associated with the vital risk and consensus approaches to waiting list management, there are important ethical principles of fairness and honesty that must be applied (Chapter 8). The following recommendations are felt to be consistent with these principles.

- The principle of 'first-on-first-off' should be a part of any fair waiting list strategy. This general principle should be preserved even though there is frequently a need to adjust the order, because of issues of relative vital risk, and to deal with unmanageable symptoms.
- Each cardiac centre should have a written waiting list policy that is readily available for inspection by members of the community at large. Because a waiting list is an admission of increased risk imposed by limited resources, the means by which distribution of this risk is to be accomplished should be open to public scrutiny.
- Each cardiac centre should have a waiting list advisory committee. The committee should comprise appropriate medical and community representatives able to represent

medical and psychosocial aspects of queue management. The committee should review past queue assignment to monitor compliance with the policy.

- A fulltime *monitor* is crucial to operation of a waiting list. Each cardiac centre should dedicate resources for this appointment. As specified above, waiting list priorities are assigned by factors that remain constant and by others that can change significantly with time. It would be the monitor's responsibility to contact all patients on the waiting list on a regular basis to review priority determinants and to screen for changing symptoms that may require urgent review.
- Each cardiovascular group should provide a forum in which physicians can fulfil their advocacy roles with respect to waiting list priority decisions. A method for appeal is important to ensure fairness.
- Special efforts should be made to ensure that patients on the list are in communication with their referring cardiologist and family physician on a regular basis during this critical waiting period. These physicians should be encouraged to report any change that will influence priority decisions.
- A large part of the morbidity on the waiting list relates to psychological stress and anxiety on the part of patients and their families. The waiting list monitor should have the responsibility of triaging trouble in this area with subsequent expeditious referral to appropriate psychosocial-spiritual counselling. It has been clearly shown that regular surveillance and contact with a sympathetic person within the waiting list monitoring process significantly reduces this anxiety (23).
- Referral to a specific surgeon or interventional cardiologist because of referring cardiologist or patient preference is widely practised across Canada. This leads inevitably to waiting list length discrepancies among surgeons. Each centre should ensure that patients know there may be surgeons with shorter waiting lists. Further, they should be told clearly that it is within their right to request a surgeon with a shorter waiting time.

9.3 INFLUENCE OF PROCEDURAL RISK ON QUEUE ASSIGNMENT

Expected long term benefits of surgery must take into account local operative mortality as well as factors that may alter mortality and morbidity expectations (26).

Parsonnet et al (26) proposed a surgical risk assessment tool that assigns risk weighting to a series of 17 risk factors. Included in this list are diabetes, age above 75 years (particularly above 80 years), reoperations, dialysis dependence, cardiogenic shock, acute renal failure, important comorbidity and coexisting need for valve surgery or repair of structural heart damage. Presence of one or more of these factors does not preclude surgery. These factors, however, do reduce and could even eliminate the mortality advantage that surgery enjoys over medical therapy, compared with a patient with similar coronary anatomy but without these procedural risk factors.

As described more completely in Chapter 1, "Revascularization options", as procedural risk rises the relative risk profiles of angioplasty and surgery need to be carefully assessed. In some situations what is a significant surgical risk factor is less of a problem for catheter intervention.

Medical conditions may modify the appropriate timing of a procedure rather than the absolute benefit to be expected when the procedure is performed. For example, with significant infections or with pulmonary embolism, delays may actually lower surgical risk. Further, minimally symptomatic patients following acute coronary syndromes with significant regions of myocardial stunning, or patients with a recent myocardial infarction, may actually benefit from a period of medical stabilization before intervention. Although reoperations carry a higher risk than the first operation, there is an important distinction that was not made by Parsonnet. When one or more grafts are patent at the time of surgery, surgical risk is higher than if no grafts are patent. This distinction is included (relative values need further discussion).

9.4 SYMPTOM STATUS

Although a decision to revascularize is driven by a blend of mortality and myocardial preservation expectations, often failure to control symptoms effectively sets the urgency level. In a waiting list management strategy, symptoms must be precisely described and frequently reviewed. In fact, the patient's very presence on the waiting list should be reviewed if symptoms improve and there is no expectation of significant mortality benefit with surgery. Symptom levels should be reassessed frequently by a skilled waiting list monitor.

Accepted clinical symptom descriptions include the differentiation between stable and unstable distinction, the Braunwald classification of unstable angina (27), the modified CCS angina classification (28) and the level of medical therapy used. Psychosocial considerations and the degree to which symptoms limit and influence quality of life are more difficult to define but nevertheless are critically important. Tools that may assist in quantifying quality-of-life variables include the Duke Activity Status Index (29) and the Seattle Angina Questionnaire (30).

TABLE 9.3

Modified Parsonnet rating system for cardiac surgical risk

Risk factor	Assigned weight
A. Factors that predict risk only and no relative surgical advantage	
Female sex	1
Morbid obesity (®1.5 x ideal weight)	3
Diabetes	3
Hypertension (SBP >140 mmHg)	3
Age (years): 70-74 75-79 ®80	7 12 20
Preoperative IABP	2
Dialysis dependency	10
Acute renal failure	10
Rare: Pacemaker dependency Paraplegia Severe asthma	2 2-10 (range too wide?) 2-10 (range too wide?)
B. Factors predicting surgical risk BUT also indicating significant surgical survival advantage over medical treatment if successful	
Ejection fraction (%): ®50 30-49 <30	0 2 4
Reoperation First (no patent grafts) Second (no patent grafts) First (patent graft[s]) Second (patent graft[s])	 3 8 5 10
Left ventricular aneurysm	5
Emergency after catheterization or PTCA	2-10
Catastrophic states Acute structural defect (VSD, MR, etc) Cardiogenic shock	10-50 Variable Variable
Mitral valve surgery PAP ®60 mmHg	5 8
Aortic valve surgery AV gradient >120 mmHg	5 7
CABG plus valve surgery (additional)	2

AV Atrioventricular; CABG Coronary artery bypass graft; IABP Intra-aortic balloon pump; MR Mitral regurgitation; PAP Pulmonary artery pressure; PTCA Percutaneous transluminal coronary angioplasty; SBP Systolic blood pressure; VSD Ventricular septal defect. Data from reference 26

9.5 "TOUGH CHOICES" AND SOCIETAL EXPECTATIONS

It has been suggested by some that "tough choices" will have to be made due to the problem of limited resources. Specifically, some have proposed a limitation of resource access by specific groups who might have "less to gain" by expensive therapies, such as the elderly or others with conditions likely to interfere with symptom-free survival. It is the opinion of this consensus that changes such as these must come from discussions at a societal level. Cardiologists and cardiovascular surgeons feel that implementation of arbitrary guidelines for financial expediency would conflict with their contract with the patient and would contravene the ethical principles cited in this report.

9.6 OBSERVATIONAL DATABASES - POTENTIAL TOOLS IN WAITING LIST MANAGEMENT

This consensus asserts that institution of a national inception-cohort observational database is fundamental to cardiovascular resource management as we approach the next century. Mortality and cost data collected in this observational database for all patients receiving diagnostic cardiac catheterization would also provide a credible basis upon which to assess the impact of therapeutic delays.

9.7 GENERAL WAITING LIST RECOMMENDATIONS

9.7.1 Where a number of angioplasty and surgical programs exist within a geographic area, waiting list management registries should be encouraged on a regional basis.

9.7.2 Although the mandate of the consensus is limited to revascularization resources, the waiting list management scheme could apply to valvular and congenital surgery as well because these procedures usually share common facilities, personnel and funding.

REFERENCES

1. Naylor CD. A different view of queues in Ontario. Health Aff (Millwood) 1991;10:110-28.
2. Anderson GM, Lomas J. Monitoring the diffusion of a technology: coronary artery bypass surgery in Ontario. Am J Public Health 1988;78:251-4.
3. Naylor CD, Morgan CD, Levinton CM, et al. Waiting for coronary revascularization in Toronto: 2 yearsâ experience with a regional referral office. Can Med Assoc J 1993;149:955-62.
4. Williams TE Jr, Fanning WJ, Leila L, et al. Can we afford to do cardiac operations in 1996? A risk-reward curve for cardiac surgery. Ann Thorac Surg 1994;58:815-21.
5. Naylor CD, Baigrie RS, Goldman BS, Basinski A. Assessment of priority for coronary revascularisation procedures. Lancet 1990;335:1070-3.
6. Rachlis MM, Olak J, Naylor CD. The vital risk of delayed coronary surgery: lessons from the randomized trials. Iatrogenics 1991;1:103-11.
7. Gersh BJ, Holmes DR Jr. Percutaneous transluminal coronary angioplasty or coronary by-pass surgery in the management of chronic angina pectoris. Int J Cardiol 1993;40:81-8.
8. Kaiser GC, Davis KB, Fisher LD, et al. Survival following coronary artery bypass grafting in patients with severe angina pectoris (CASS). An observational study. J Thorac Cardiovasc Surg 1985;89:513-24.
9. Mock MB, Fisher LD, Holmes DR Jr, et al. Comparison of effects of medical and surgical therapy on survival in severe angina pectoris and two-vessel coronary artery disease with and without left ventricular dysfunction: a Coronary Artery Surgery Study Registry study. Am J Cardiol 1988;61:1198-203.
10. Eleven-year survival in the Veterans Administration randomized trial of coronary bypass surgery for stable angina: The Veterans Administration Coronary Artery Bypass Surgery Cooperative Study Group. N Engl J Med 1984;311:1333-9.

11. Prospective randomized study of coronary artery bypass surgery in stable angina pectoris: a progress report on survival. Circulation 1982;65:67-71.

12. Bogaty P, Dagenais GR, Cantin B, Alain P, Rouleau JR. Prognosis in patients with a strongly positive exercise electrocardiogram. Am J Cardiol 1989;64:1284-8.

13. Little WC, Constantinescu M, Applegate RJ, et al. Can coronary angiography predict the site of a subsequent myocardial infarction in patients with mild-to-moderate coronary artery disease? Circulation 1988;78:1157-66.

14. Morin JE, Symes JF, Guerraty AJ, Poirier NL, Sampalis J. Coronary artery bypass profile in Canada and the United States. Can J Cardiol 1990;6:319-22.

15. Luchi RJ, Scott SM, Deupree RH. Comparison of medical and surgical treatment for unstable angina pectoris: results of a Veterans Administration Cooperative Study. N Engl J Med 1987;316:977-84.

16. Peters S, Chagani K, Paddon P, et al. Coronary artery bypass surgery in Canada. Health Rep 1990;2:9-26.

17. Braunwald E, Jones RH, Mark DB, et al. Diagnosing and managing unstable angina. Circulation 1994;90:613-22.

18. Rizik DG, Healy S, Margulis A, et al. A new clinical classification for hospital prognosis of unstable angina pectoris. Am J Cardiol 1995;75:993-7.

19. Spence PA, Gray LA Jr. New conduits for coronary artery bypass: great promise for improved outcome from coronary artery surgery. J Ky Med Assoc 1994;92:52-8.

20. Unstable angina pectoris: National Cooperative Study Group to compare surgical and medical therapy. II: In-hospital experience and initial follow-up results in patients with one, two and three vessel disease. Am J Cardiol 1978;42:839-48.

21. Cameron AA, Green GE, Brogno DA, Thornton J. Internal thoracic artery grafts: 20-year clinical follow-up. J Am Coll Cardiol 1995;25:188-92.

22. Christakis G, Ivanov J, Weisel RD, et al. The changing pattern of coronary artery bypass surgery. Circulation 1989;80:I151-61.

23. Cox JL, Petrie JF, Pollak PT, Johnstone DE. Managed delay for coronary artery bypass graft surgery. The experience at one Canadian centre. J Am Coll Cardiol 1996;27:1365-73.

24. Higginson LAJ, Cairns JA, Keon WJ, Smith ER. Rates of cardiac catheterization, coronary angioplasty and open-heart surgery in adults in Canada. Can Med Assoc J 1992;146:921-5.

25. Naylor CD, Levinton CM, Baigrie RS. Adapating to waiting lists for coronary revascularization. Do Canadian specialists agree on which patients come first? Chest 1992;101:715-22.

26. Parsonnet V, Dean D, Bernstein AD. A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart disease. Circulation 1989;79:I3-12.

27. Braunwald E. Unstable angina: a classification. Circulation 1989;80:410-4.

28. Campeau L. Grading of angina pectoris. Circulation 1975;54:522-3.

29. Hlatky MA, Boineau RE, Higginbotham MB, et al. A brief self-administered questionnaire to determine functional capacity (the Duke Activity Status Index). Am J Cardiol 1989;64:651-4.

30. Spertus JA, Winder JA, Dewhurst TA, et al. Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease. J Am Coll Cardiol 1995;25:333-41.

31. Takaro T, Peduzzi P, Detre KM, et al. Survival in subgroups of patients with left main coronary artery disease. Veterans Administration cooperative study of surgery for coronary arterial occlusive disease. Circulation 1982;66:14-22.