

European Criteria for the Appropriateness and Necessity of Coronary Revascularization Procedures

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INTRODUCTION

Large variations in the use of coronary revascularization procedures have been documented among and within countries. In Europe, for example, the rate of coronary artery bypass surgery (CABG) per 100,000 population in 1992 varied from 14 in Spain, to 31 in the United Kingdom, to 61 in the Netherlands (1). In North America, the age-adjusted rate of CABG surgery in 1993 was 1.8 times greater for patients in New York State than it was in Canada, and it was 2.2 times greater in the case of percutaneous transluminal coronary angioplasty (PTCA) (2). Such differences do not appear to be related to major differences in the prevalence of coronary artery disease in these countries, and they raise questions as to whether some patients are receiving inappropriate procedures or others are not receiving necessary ones.

One approach to answering these kinds of questions is the RAND appropriateness method, which has been applied in a number of countries since the mid 1980s to obtain ratings of the appropriateness and necessity of various medical and surgical procedures. In Europe, appropriateness panels using this method to rate coronary revascularization procedures have been carried out in Spain (3), Sweden (4), Switzerland (5), the Netherlands (6) and the United Kingdom (7), while in North America, both the United States (8) and Canada (9) have held such panels. The RAND method is based on a review of the scientific literature and the work of an expert panel which rates the appropriateness, and sometimes the necessity, of a comprehensive list of indications for the procedure in question. Appropriateness criteria have most often been used in retrospective audits of patients who have undergone the procedure, to determine the proportion of those who received inappropriate procedures, that is, to measure the overuse of procedures. Necessity criteria, on the other hand, can be used to measure the underuse of procedures by applying them to patients were potential candidates for the procedure, to determine which ones meeting necessity criteria did not receive the procedure.

Until now, however, the criteria produced using this method have all been from single-country panels, on the theory that differences in values or clinical practice style make it advisable for each country to produce its own appropriateness criteria. In recent years, however, European countries have been moving toward ever greater political, economic and social integration, a trend that is likely to extend to the area of medical care, as well. Just as the introduction of a common currency may lead to reduced economic

disparities among member countries, so the development of common tools to measure the quality of medical care has the potential to help reduce clinical practice variations that are unrelated to relevant variables in the patient population. Such considerations led us to consider the feasibility of holding an appropriateness panel made up of specialists from a number of different countries, which would have the added benefit of economies of scale in comparison to carrying out multiple national panels on the same subject. Thus, as part of a European Commission BIOMED Concerted Action on the appropriateness of medical and surgical procedures, we carried out a multinational European panel that rated the appropriateness and necessity of PTCA and CABG in 1999.

METHODS

Fifteen physicians were recruited from five European countries (the Netherlands, Spain, Sweden, Switzerland and the United Kingdom) to serve on the expert panel. Panelists were initially selected from lists of those who had previously served on appropriateness panels in their own country, most of whom had been chosen from nominations by their respective medical societies. Where this was not possible, organizers of previous national level panels were asked to recommend other persons with recognized prestige in their respective specialties. The original plan was to have one interventional cardiologist (IC), one non-interventional cardiologist (NIC) and one cardiovascular surgeon (CVS) from each country, however, the need for some substitutions resulted in a final panel composition of three NICs, seven ICs and five CVSs. In all, 27 specialists were contacted to fill the 15 panel slots. All three of the Spanish panelists contacted accepted the invitation, while two prospective panelists from Sweden, two from the Netherlands, two from the United Kingdom and six from Switzerland declined the invitation to serve on the panel. Six of the twelve persons who declined cited reasons related to conflicting travel or work arrangements, three expressed concerns about the amount of work involved, and three gave no reason for their inability to participate. No financial remuneration was provided for the panel work other than reimbursement of expenses for travel and accommodations.

Three working documents were produced for the panel process. First, the Swedish Council on Technology Assessment in Health Care (SBU) carried out a comprehensive review and synthesis of the findings of selected English-language studies on the efficacy and risks of PTCA and CABG published between April 1993 and December 1997 (10). This document supplemented earlier reviews of the literature by RAND and SBU, which were also available to the panel (4,11,12). Second, the panel coordinators prepared a list of 400 detailed clinical scenarios, which described hypothetical patients who might be considered for coronary revascularization. Most of these scenarios were rated twice: first, for the appropriateness of PTCA and second, for the appropriateness of CABG, giving a total of 740 ratings or "indications". The clinical scenarios describing patients with acute myocardial infarction were rated only once, for the appropriateness of PTCA. The list of indications was based on previous lists used in different national-level appropriateness panels, but was reduced to focus on those indications that had been shown to represent substantial numbers of real patients when they were applied to patient populations in those countries. The indications were grouped into four "chapters" representing the primary clinical conditions presented by patients referred for revascularization: chronic stable angina, hospital admission for unstable angina, acute myocardial infarction (first 12 hours) and post-myocardial infarction (>12 hours - 28 days). Each chapter was further subdivided by variables describing the extent of vessel disease, ejection fraction, stress test results, surgical risk and other factors. An example of a specific indication is a patient with severe angina (Class III/IV), who has 1- or 2-vessel disease with proximal left anterior descending (PLAD) involvement, a very positive stress test, a left ventricular ejection fraction (EF) between 30% and <50%, who is at high surgical risk. The third panel document contained a precise definition of each term used in the list of indications, to assure that panelists had the same understanding of what constituted, for example, a "very positive stress test" or "high surgical risk."

The synthesis of the evidence, list of indications and definitions were mailed to each panelist, with the request that they rate each clinical scenario for the appropriateness of PTCA and the appropriateness of CABG on a scale of 1 to 9, where 1 meant the procedure was highly inappropriate and 9 meant it was highly appropriate. An *appropriate* procedure was defined as one in which : "The expected health benefit

(e.g., increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (e.g., mortality, morbidity, anxiety, pain, time lost from work) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost" (12). Panel members completed these first-round ratings independently, with no knowledge of the identity of their fellow panel members. The rating sheets were then returned to the project coordinators for data entry and analysis.

Following this first round of ratings, panelists were invited to a meeting in Madrid where they were able to see the results of the ratings (the frequency of panel responses together with their own rating for each indication) and discuss areas of confusion or disagreement. Thirteen of the fifteen panelists attended the meeting: six ICs, two NICs and five CVSSs. The meeting was conducted in English and led by a moderator experienced in applying the RAND appropriateness method. Based on an analysis of the distribution of ratings for each indication in the first round, the moderator focused the discussion on those areas where panelists seemed to be widely polarized in their appropriateness judgments. As with all panels using the appropriateness method, there was no attempt to force the panel to consensus, although the panelists were encouraged to support their judgments by citing the relevant scientific evidence. During the panel meeting, minor changes were made to the list of indications, with the result that the revised list consisted of 430 clinical scenarios and 842 indications. For example, indications that were originally grouped together for mild/moderate angina (class I/II) were split into two categories, one for angina class I and the other for angina class II. After the discussion of each chapter in the list of indications, panelists rated all the indications in that chapter a second time.

The final appropriateness criteria were based on the median panel rating and level of disagreement for each indication in the second round, using the following definitions: all indications with a median rating of 7-9, rated without disagreement, were classified as appropriate; those with a median rating of 1-3, rated without disagreement, were classified as inappropriate; and those with a median rating of 4-6, as well as all indications rated with disagreement, regardless of the median, were classified as uncertain. An indication was considered to be rated "with disagreement" when at least four panelists rated it in the 1-3 range, and at least 4 panelists rated it in the 7-9 range.

To produce necessity criteria, a third round of panel ratings was carried out by mail, in which panelists were asked to rate the necessity of performing coronary revascularization for the 288 indications that had previously been classified as appropriate for either PTCA or CABG. A procedure was defined as necessary if it met all four of the following criteria: (1) the procedure is appropriate, i.e., the health benefits exceed the risks by a sufficient margin to make it worth doing; (2) it would be improper care not to offer the procedure to a patient; (3) there is a reasonable chance that the procedure will benefit the patient; and 4) the magnitude of the expected benefit is not small (12). These indications were rated on a similar 1-9 scale, in which 1 meant that coronary revascularization was appropriate but not necessary for the particular indication, and 9 meant that it was appropriate and necessary. All indications with a median rating of 7-9, without disagreement, were classified as necessary for coronary revascularization.

In accordance with the preceding definitions, each clinical scenario in the list of indications was classified as "necessary" (and therefore appropriate), "appropriate" (but not necessary), "uncertain", or "inappropriate". For all indications in which coronary revascularization was classified as "necessary", then whichever of the two procedures had previously been classified as appropriate was reclassified as necessary. If both PTCA and CABG had previously been classified as appropriate, then both ratings were changed to necessary. Thus, if both PTCA and CABG are rated necessary for a particular indication, this means that coronary revascularization is necessary for this patient, and the panel considered that there were no clinical grounds for strongly preferring one procedure over the other.

After classifying each indication, a detailed review was made of the entire list to check the internal consistency of the ratings. The purpose of this review was to determine if there were conflicting patterns of recommendations for either procedure. For example, if PTCA was normally rated more appropriate in patients with stenosis of the PLAD artery than in similar patients without PLAD involvement, then any

reversal of this pattern was highlighted as a possible inconsistency. Fifteen potential inconsistencies were detected out of the 842 indications rated in the second round. The panelists received a worksheet describing each inconsistency and the clinical question on which it was based, and were asked to consider whether the appropriateness classification should be revised to make the criteria more internally consistent. If a majority of the panelists voted in favor of the revision, then the classification was changed.

RESULTS

Overall, 24% of the PTCA indications (n=430) were rated appropriate and necessary, 16% were appropriate, 43% were uncertain, and 17% were inappropriate. The corresponding figures for CABG (n=412) were 33% appropriate and necessary, 7% appropriate, 40% uncertain and 20% inappropriate.

Tables 1 and 2 show the percentage of indications classified in each appropriateness category, by chapter (i.e., clinical presentation) for PTCA and CABG, respectively. PTCA was considered necessary for over half of all indications in the AMI chapter and for more than one-third of all indications in the unstable angina chapter. Less than one-fifth of the chronic stable angina and post-AMI indications were judged necessary. In the case of CABG, all indications that were rated appropriate for unstable angina were also considered necessary (42%). Since CABG typically cannot be performed within the first 12 hours of a myocardial infarction, the panel was not asked to rate that procedure for the AMI chapter. The largest proportion of inappropriate indications was in the post-AMI chapter for both PTCA (23%) and CABG (23%).

Table 1. Percentage of indications for PTCA rated in each appropriateness category, by chapter					
Chapter	No. of indicat.	Appropriateness category (%)			
		N	A	U	I
Chronic stable angina	204	19	23	44	15
Unstable angina	114	36	9	39	16
Acute myocardial infarction (AMI)	18	56	17	22	6
Post AMI	94	15	10	52	23
All chapters	430	24	16	43	17
PTCA, percutaneous transluminal coronary angioplasty					
N, necessary; A, appropriate; U, uncertain; I, inappropriate					

Table 1

Table 2. Percentage of indications for CABG rated in each appropriateness category, by chapter					
Chapter	No. of indicat.	Appropriateness category (%)			
		N	A	U	I
Chronic stable angina	204	32	10	40	19
Unstable angina	114	42	0	38	20
Acute myocardial infarction (AMI)*		--	--	--	--
Post AMI	94	26	9	43	23
All chapters	412	33	7	40	20
CABG, coronary artery bypass graft surgery					
N, necessary; A, appropriate; U, uncertain; I, inappropriate					
* CABG was not rated for AMI indications					

Table 2

The panelists disagreed on 4% of the PTCA indications and 7% of those for CABG. Most of the indications rated with disagreement were in the chronic stable angina chapter. There was no significant difference in the amount of disagreement between the two procedures ($p=0.09$). The panelists disagreed on 7% of the 288 indications rated for necessity.

The 15 potential clinical inconsistencies (8 for PTCA and 7 for CABG) were primarily for cases where the median panel rating was on the borderline between "appropriate" and "uncertain", so that a 1-point shift in rating by one panelist would have changed the appropriateness classification. In only two cases, where the panel rated the appropriateness of CABG for a patient with 1- or 2-vessel disease without PLAD involvement and a normal ($\geq 50\%$) ejection fraction, was the inconsistency due to disagreement among the panelists. For each of the inconsistencies that the panelists were asked to consider, at least 8 panelists voted in favor of revising the appropriateness classification to make it more internally consistent with the panel's recommendations for similar patients. As a result, 9 indications were changed from appropriate to uncertain, 5 indications from uncertain to appropriate, and 1 indication from inappropriate to uncertain. The figures in table 1 were calculated taking these changes into account.

The final appropriateness and necessity criteria are shown in [Annex I](#) (Fig. 1a, 1b, 1c, 2, 3, 4). The clinical scenario describing a particular patient can be found by first identifying the major presenting symptom (chronic stable angina, unstable angina, acute myocardial infarction or post-myocardial infarction) and consulting the corresponding chapter. Within each chapter, one can then locate the intersection of row and column variables describing the patient being considered for revascularization. In the chronic stable angina chapter, for example, the variables described in the rows are extent of vessel disease, stress test results and left ventricular ejection fraction. The level of surgical risk is shown in the column headings. The complete list of definitions to which the panelists referred when rating the indications is shown in [Annex II](#).

DISCUSSION

Although many individual countries in both Europe and North America have applied the appropriateness method to develop criteria for coronary revascularization procedures, this was the first cross-national attempt to develop such criteria. This experience has shown that a multispecialty group of experts from

different European countries are able to work together to formulate appropriateness criteria that may be useful both as a yardstick to measure past performance and as an aid to physicians in making treatment decisions about individual patients.

It might be expected that panelists from a number of different countries would find it harder to agree on their appropriateness ratings than panelists from a single-country panel. In fact, we found this was not so. We defined disagreement to mean that at least one-third of the panel members rated an indication a 1, 2 or 3, and at least one-third rated it a 7, 8 or 9. The total amount of disagreement measured in this way in the second-round appropriateness ratings was 5%. A comparable all-Spanish panel that rated the appropriateness of PTCA and CABG in 1997 disagreed on substantially more indications (13%),³ while an all-Dutch panel composed of six interventional cardiologists and six cardiovascular surgeons disagreed on 3.2% of the indications rated (6).

The results of two other multinational appropriateness panels, also sponsored by the BIOMED Concerted Action on the appropriateness of medical and surgical procedures, bore out our positive experience. In Switzerland, a multispeciality panel of 14 experts from nine European countries rated the appropriateness and necessity of upper and lower gastrointestinal endoscopy procedures (13), while in The Netherlands, a panel of 15 urologists from five European countries rated the appropriateness of treatment of benign prostatic hyperplasia (BPH) (14). Concerns about how differently a multinational panel might rate appropriateness in comparison to a single-country panel led the investigators of the BPH study to conduct an all-Dutch panel concurrently with the multinational one. Interpanel agreement in classifying appropriateness was found to be high, with 84% of the indications classified identically (Kappa = 0.76). In both of these multinational panels, disagreement among panel members was also quite low: about 6% in the endoscopy panel (15) and 1% in the BPH panel (14).

Physicians and policy makers interested in how appropriateness and necessity criteria can be used to improve medical care may have concerns about the reliability and validity of the RAND method. Although panelists are carefully selected and provided with an extensive literature review of the procedure to be evaluated, their ratings will in some sense be subjective and dependent on each expert's knowledge and experience. Thus, the selection of a different group of experts would undoubtedly lead to at least some of the recommendations being classified differently. In the most extensive test to date of the reproducibility of the appropriateness method, experts were randomly assigned to three different panels to rate coronary revascularization. The resulting three-way kappa for the classification of appropriateness was moderately high (0.52), which is about the same for many diagnostic tests, while the three-way kappa for the classification of necessity was very high (0.83) (16). The validity of necessity criteria is supported by several studies showing that patients who met necessity criteria and did not undergo revascularization had worse outcomes than similar patients who underwent revascularization (17,18).

There may also be concerns that the inclusion of panelists from different countries could reduce panel reliability. However, we have not found systematic differences by nationality in the appropriateness ratings of the multinational panel (19). As noted above, a comparison between a Dutch and a multinational panel found very high levels of agreement for BPH indications (14). Similar comparisons could be made between criteria developed by physicians from one country and those of a multinational panel. Some clinicians may consider that additional clinical variables should be included in the rating structure, such as the morphological characteristics of the lesions. Several previous panels that rated the appropriateness of PTCA and CABG used this approach by including classification of lesion type (A,B or C) in their lists of indications (4, 6). Our study did not incorporate this variable, however, in line with the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for PTCA (20). Although lesion type was included in the original 1988 ACC/AHA guidelines for PTCA, patients were subsequently classified as low or high risk candidates for PTCA based on a combination of their clinical characteristics and lesion type. In addition, risk estimates are extremely unstable for specific lesion characteristics (21). This exemplifies the difficulties that arise in developing criteria when only limited data are available.

The RAND appropriateness method is only one of several techniques that have been used to develop

recommendations for treatment decisions. Alternative methods include decision-analysis, meta-analysis and cost-effectiveness analysis. These quantitative techniques usually result in a recommended treatment or an estimated probability of an outcome for different treatment choices. In contrast to an expert panel, decision analysts try to incorporate only data that has been validated in the literature. However, expert panelists do not base their recommendations solely on opinion, and decision analysts often add expert opinion to their models (22). We chose to use the RAND appropriateness method because it has been shown to be a reasonably valid and reliable tool for coronary revascularization decisions (16, 17).

How, then, might these criteria be used? Historically, they have most often been used as a measure of past performance. For example, the clinical charts of patients who have undergone coronary revascularization are reviewed in order to obtain the information necessary to classify each patient in the list of indications. It can then be determined if the procedure received was appropriate, uncertain or inappropriate according to the panel's recommendations. These types of retrospective chart audits have been carried out in most of the European countries that were represented on our panel, using the criteria developed by their own national-level panels. The proportion of procedures classified as inappropriate in such studies can be considered an approximate measure of "overuse." Necessity criteria, on the other hand, can be applied to patients who might have been candidates for coronary revascularization, for example, by studying patients who have undergone coronary angiography to determine which ones meeting a "necessity" criterion did not receive a revascularization procedure (excluding those who were offered but refused the procedure). This type of study, to measure the "underuse" of coronary revascularization, has been carried out in the United States (23,24), Sweden (25) and the United Kingdom (18). One advantage of using criteria developed by multinational panels in these types of studies is that the same set of criteria can be applied to each of the participating countries, allowing cross-national comparisons.

Perhaps the greater challenge is the prospective use of the criteria to help physicians and patients decide when it is appropriate (or necessary) to perform a revascularization procedure. By publishing the complete list of recommendations herein, we encourage physicians to consult the criteria when making their decisions. It should be emphasized, however, that these are only recommendations, representing a combination of the best scientific evidence available together with the judgments of medical experts involved in referring patients for or performing the procedure under study. Appropriateness panels are typically instructed to base their judgments on an "average patient" presenting to an "average physician" in an "average hospital." Although the list of indications is designed to be highly specific, there may well be special circumstances not reflected in the clinical scenarios that support a different decision. Such departures from the recommendations, however, should not be arbitrary, and physicians should be able to justify their reasons for not following the criteria in particular instances. With these caveats in mind, it is considered that routine consultation of the criteria could well result in a reduction of the large variations in procedure rates that are currently seen in clinical practice.

It should be emphasized that the indications discussed in this paper are only for theoretical combinations of variables describing patient symptoms and diagnostic tests. Patients are not distributed uniformly across the different clinical scenarios, and some indications may represent few real patients. Nevertheless, the large proportions of indications that our panel rated as necessary for acute conditions may suggest potential underuse of coronary revascularization procedures in the population. Even in the United States - where coronary revascularization rates are much higher than in Europe - substantial underuse has been shown to occur (23, 24). The existence of multinational necessity criteria offers the opportunity to determine if a similar phenomenon is also occurring in European countries.

A major limitation in the area of appropriateness research relates to the difficulties involved in disseminating and using the panel criteria, and particularly on how to keep the panel recommendations up-to-date in light of new scientific evidence. One way to do this is by making the criteria available in a dynamic format such as the worldwide web. Ideally, links to the supporting scientific evidence could also be provided where such evidence exists. The criteria developed by the multinational endoscopy panel are currently available on a website (<http://www.epage.ch>) This type of interactive tool is much easier to use

than a paper format, and has the added capability of being quickly and easily updated when new evidence becomes available.

In summary, our experience suggests that multinational panels show promise as a feasible and practical way of addressing appropriateness and necessity issues in countries sharing similar levels of socioeconomic development and medical technology. The criteria for coronary revascularization procedures presented in [Annex I](#) (Fig. 1a, 1b, 1c, 2, 3, 4) represent the combined judgments of a highly experienced group of experts in cardiology and cardiovascular surgery from five European countries. They can be used as yardsticks to measure performance and to compare appropriateness across countries, as well as guides for prospective decision making. Current formats for presenting these types of criteria, however, have limited their dissemination and use. New ways need to be found to make the criteria more flexible and to keep them updated in accordance with the latest scientific evidence. As Internet technology becomes more widely available and reliable, appropriateness recommendations can be modified to keep pace with the results of new research and can be more easily accessed and used by both physicians and patients.

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ANNEX I. Appropriateness and Necessity Ratings for PTCA and CABG, Multinational European Panel, 1999

Chapter 1: CHRONIC STABLE ANGINA	Low/Moderate		High	
	Surgical Risk		Surgical Risk	
	PTCA	CABG	PTCA	CABG
A. SEVERE ANGINA (CLASS III/IV)				
1. Left main disease	I	N	I	N
2. Three vessel disease*	U	N	U	N
3. One or two vessel disease with PLAD				
a) With very positive stress test*	N	N	N	N
b) With moderately positive stress test				
1) EF \geq 50%	N	N	N	N
2) EF \geq 30- $<$ 50%	N	N	N	N
3) EF \geq 20- $<$ 30%	U	N	N	N
c) With stress test indeterminate or not done*	U	N	N	U
d) With negative stress test*	U	U	U	U
4. One or two vessel disease without PLAD				
a) With very positive stress test*	N	N	A	U
b) With moderately positive stress test*	A	A	A	U
c) With stress test indeterminate or not done				
1) EF \geq 50%	A	U	A	I
2) EF \geq 30- $<$ 50%	A	U	A	U
3) EF \geq 20- $<$ 30%	A	U	A	U
d) With negative stress test				
1) EF \geq 50%	U	I	U	I
2) EF \geq 30- $<$ 50%	U	I	U	I
3) EF \geq 20- $<$ 30%	U	U	U	I

N= Necessary A= Appropriate U= Uncertain I= Inappropriate

PLAD = proximal left anterior descending artery

* Indicates that the appropriateness and necessity ratings were the same for all three ejection fraction categories, therefore they are shown only once.

An N in both the PTCA and CABG column means that revascularization was rated "necessary" for coronary revascularization in that patient, and that the panel did not strongly prefer one procedure over the other.

Figure 1a

Chapter 1: CHRONIC STABLE ANGINA

	Low/Moderate		High	
	Surgical Risk		Surgical Risk	
	PTCA	CABG	PTCA	CABG
B. MODERATE ANGINA (CLASS II)				
1. Left main disease	I	N	I	N
2. Three vessel disease				
a) With very positive stress test*	U	N	U	N
b) With moderately positive stress test				
1) EF \geq 50%	U	N	U	A
2) EF \geq 30- $<$ 50%	U	N	U	N
3) EF \geq 20- $<$ 30%	U	N	U	N
c) With stress test indeterminate or not done				
1) EF \geq 50%	U	A	U	A
2) EF \geq 30- $<$ 50%	U	A	U	A
3) EF \geq 20- $<$ 30%	U	N	U	A
d) With negative stress test*	U	U	U	U
3. One or two vessel disease with PLAD				
a) With very positive stress test*	N	N	N	N
b) With moderately positive stress test				
1) EF \geq 50%	N	N	A	A
2) EF \geq 30- $<$ 50%	N	N	N	N
3) EF \geq 20- $<$ 30%	N	N	N	A
c) With stress test indeterminate or not done*	A	U	A	U
d) With negative stress test*	U	U	U	U
4. One or two vessel disease without PLAD				
a) With very positive stress test				
1) EF \geq 50%	A	A	A	U
2) EF \geq 30- $<$ 50%	N	N	A	U
3) EF \geq 20- $<$ 30%	A	A	A	U
b) With moderately positive stress test				
1) EF \geq 50%	A	U	A	I
2) EF \geq 30- $<$ 50%	A	U	A	U
3) EF \geq 20- $<$ 30%	A	U	A	U
c) With stress test indeterminate or not done*	U	U	U	I
d) With negative stress test*	I	I	I	I

Figure 1b

Chapter 1: CHRONIC STABLE ANGINA	Low/Moderate		High	
	Surgical Risk		Surgical Risk	
	PTCA	CABG	PTCA	CABG
C. MILD ANGINA (CLASS I)				
1. Left main disease	I	N	I	N
2. Three vessel disease				
a) With very positive stress test*	U	N	U	N
b) With moderately positive stress test*	U	N	U	A
c) With stress test indeterminate or not done				
1) EF \geq 50%	I	A	U	U
2) EF \geq 30- $<$ 50%	I	A	I	U
3) EF \geq 20- $<$ 30%	I	A	I	U
d) With negative stress test				
1) EF \geq 50%	I	U	U	U
2) EF \geq 30- $<$ 50%	I	U	I	U
3) EF \geq 20- $<$ 30%	I	U	I	U
3. One or two vessel disease with PLAD				
a) With very positive stress test				
1) EF \geq 50%	N	N	N	U
2) EF \geq 30- $<$ 50%	N	N	N	U
3) EF \geq 20- $<$ 30%	N	U	N	U
b) With moderately positive stress test				
1) EF \geq 50%	A	A	A	U
2) EF \geq 30- $<$ 50%	N	N	A	U
3) EF \geq 20- $<$ 30%	N	U	A	U
c) With stress test indeterminate or not done*	U	U	U	I
d) With negative stress test*	U	U	U	I
4. One or two vessel disease without PLAD				
a) With very positive stress test				
1) EF \geq 50%	A	U	A	I
2) EF \geq 30- $<$ 50%	N	U	A	U
3) EF \geq 20- $<$ 30%	A	U	A	U
b) With moderately positive stress test				
1) EF \geq 50%	A	U	A	I
2) EF \geq 30- $<$ 50%	A	U	A	I
3) EF \geq 20- $<$ 30%	U	U	U	I
c) With stress test indeterminate or not done*	I	I	U	I
d) With negative stress test*	I	I	I	I

Figure 1c

Chapter 2: UNSTABLE ANGINA

	Low/Moderate		High	
	Surgical Risk		Surgical Risk	
	PTCA	CABG	PTCA	CABG
A. ONGOING SYMPTOMS DESPITE IV NITRATES (UNABLE TO WITHDRAW NITRATES)				
1. Left main disease	I	N	I	N
2. Three vessel disease*	U	N	N	N
3. One or two vessel disease with PLAD*	N	N	N	N
4. One or two vessel disease without PLAD*	N	U	N	U
B. ISCHEMIA NOT REQUIRING IV NITRATES				
1. Left main disease	I	N	I	N
2. Three vessel disease*	U	N	N	N
3. One or two vessel disease with PLAD*	N	N	N	N
4. One or two vessel disease without PLAD*	N	N	N	U
C. NO ONGOING SYMPTOMS AND NOT ON IV NITRATES				
1. Left main disease	I	N	I	N
2. Three vessel disease				
a) With very positive stress test*	U	N	U	N
b) With moderately positive stress test*	U	N	U	U
c) With stress test indeterminate or not done*	U	U	U	U
d) With negative stress test				
1) EF \geq 50%	I	U	I	I
2) EF \geq 30- $<$ 50%	I	U	I	I
3) EF \geq 20- $<$ 30%	I	U	I	U
3. One or two vessel disease with PLAD				
a) With very positive stress test*	N	N	N	U
b) With moderately positive stress test				
1) EF \geq 50%	N	N	A	U
2) EF \geq 30- $<$ 50%	N	N	A	U
3) EF \geq 20- $<$ 30%	U	N	A	U
c) With stress test indeterminate or not done*	U	U	U	I
d) With negative stress test*	U	U	U	I
4. One or two vessel disease without PLAD				
a) With very positive stress test*	N	U	A	U
b) With moderately positive stress test				
1) EF \geq 50%	A	U	A	I
2) EF \geq 30- $<$ 50%	A	U	A	I
3) EF \geq 20- $<$ 30%	U	U	U	I
c) With stress test indeterminate or not done*	U	I	U	I
d) With negative stress test*	I	I	I	I

Figure 2

Chapter 3: ACUTE MYOCARDIAL INFARCTION*		
(first 12 hours)		PTCA
A. WITHIN 6 HOURS AFTER SYMPTOM ONSET		
1. Strong contraindications to thrombolytic therapy		
1) MI is complicated by:		
a) Persistent chest pain		N
b) Cardiogenic shock or persistent pulmonary edema		N
2) MI is an uncomplicated Q-wave infarct		A
2. No strong contraindications to thrombolytic therapy		
a. Has not yet received thrombolytic therapy		
1) MI is complicated by:		
a) Persistent chest pain		A
b) Cardiogenic shock or persistent pulmonary edema		N
2) MI is an uncomplicated Q-wave infarct		U
b. Has received thrombolytic therapy		
1) MI is complicated by:		
a) Persistent chest pain		N
b) Cardiogenic shock or persistent pulmonary edema		N
2) MI is an uncomplicated Q-wave infarct		I
B. BETWEEN 6 AND 12 HOURS AFTER SYMPTOM ONSET		
1. Strong contraindications to thrombolytic therapy		
1) MI is complicated by:		
a) Persistent chest pain		N
b) Cardiogenic shock or persistent pulmonary edema		N
2) MI is an uncomplicated Q-wave infarct		U
2. No strong contraindications to thrombolytic therapy		
a. Has not yet received thrombolytic therapy		
1) MI is complicated by:		
a) Persistent chest pain		A
b) Cardiogenic shock or persistent pulmonary edema		N
2) MI is an uncomplicated Q-wave infarct		U
b. Has received thrombolytic therapy		
1) MI is complicated by:		
a) Persistent chest pain		N
b) Cardiogenic shock or persistent pulmonary edema		N
2) MI is an uncomplicated Q-wave infarct		U

* In this chapter panelists were asked to rate "the appropriateness of performing coronary angiography and angioplasty (if technically feasible) of the culprit lesion."

Figure 3

Chapter 4: POST-MYOCARDIAL INFARCTION	Low/Moderate		High	
	Surgical Risk PTCA	CABG	Surgical Risk PTCA	CABG
A. ANGINA POST-INFARCTION				
1. Left main disease	I	N	I	N
2. Three vessel disease*	U	N	U	N
3. One or two vessel disease with PLAD				
1) EF \geq 50%	N	N	N	U
2) EF \geq 30- $<$ 50%	N	N	N	U
3) EF \geq 20- $<$ 30%	N	N	N	N
4. One or two vessel disease without PLAD*	N	U	A	U
B. ASYMPTOMATIC				
1. Left main disease	I	N	I	N
2. Three vessel disease				
a) With very positive stress test*	U	N	U	N
b) With moderately positive stress test				
1) EF \geq 50%	U	A	U	A
2) EF \geq 30- $<$ 50%	U	N	U	A
3) EF \geq 20- $<$ 30%	U	A	U	A
c) With stress test indeterminate or not done*	U	A	U	U
d) With negative stress test*	I	U	I	U
3. One or two vessel disease with PLAD				
a) With very positive stress test				
1) EF \geq 50%	N	N	N	U
2) EF \geq 30- $<$ 50%	N	N	N	U
3) EF \geq 20- $<$ 30%	U	N	N	U
b) With moderately positive stress test*	U	U	U	U
c) With stress test indeterminate or not done*	U	U	U	U
d) With negative stress test*	I	I	I	I
4. One or two vessel disease without PLAD				
a) With very positive stress test				
1) EF \geq 50%	A	U	A	I
2) EF \geq 30- $<$ 50%	A	U	A	I
3) EF \geq 20- $<$ 30%	A	U	A	U
b) With moderately positive stress test				
1) EF \geq 50%	U	U	U	I
2) EF \geq 30- $<$ 50%	U	U	U	I
3) EF \geq 20- $<$ 30%	U	U	U	U
c) With stress test indeterminate or not done*	U	I	U	I
d) With negative stress test*	I	I	I	I

Figure 4

ANNEX II. DEFINITIONS USED BY THE MULTINATIONAL EUROPEAN PANEL FOR RATING THE APPROPRIATENESS AND NECESSITY OF CORONARY REVASCULARIZATION

1. **PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)**: Percutaneous coronary revascularization using conventional balloon catheter or other device (atherectomy, stent, laser).

2. **CORONARY ARTERY BYPASS GRAFTING (CABG)**: Coronary revascularization by surgical opening of the thorax.

3. **CHRONIC STABLE ANGINA**: Angina that is routinely provoked by exercise, which subsides with rest or following administration of nitroglycerin. Severity is classified in accordance with the criteria of the Canadian Cardiovascular Society:

Class I: Angina does not limit ordinary physical activity. Angina provoked by strenuous, rapid, or prolonged exertion or activity.

Class II: Angina limits ordinary physical activity. Angina provoked by moderate exertion or activity:

- Walking or climbing stairs rapidly
- Walking uphill
- Walking more than two blocks or climbing more than one flight of stairs
- Angina with cold, wind, stress, or after getting up in the morning.

Class III: Angina strongly limits ordinary physical activity. Angina provoked by slight exertion or activity:

- Walking one or two blocks on the level or climbing one flight of stairs.

Class IV: Angina can be present at rest, or provoked by minimal exertion or activity.

4. **UNSTABLE ANGINA:** Pain due to myocardial ischemia which requires hospitalization due to difficulty of control or to rule out acute myocardial infarction. Includes:

- Chronic angina increasing in intensity, frequency, or duration
- Development of angina at rest
- Recent onset of severe angina.

5. **ACUTE MYOCARDIAL INFARCTION (AMI):** Presence of at least 2 of the following criteria:

- Anginal pain at least 15 minutes in duration
- Elevation of enzyme levels used to diagnose AMI (CK) to at least double the normal range of values
- Elevation of ST greater than 1 mm in at least 2 standard limb leads or in 3 precordials, or development of Q waves in the ECG.

The **acute phase** of infarction is considered to be the first 12 hours after onset of pain.

Cardiogenic shock is considered as the presence of at least 2 of the following criteria:

- Systolic hypotension \leq mmHg in the presence of inotropic drugs or \leq 90 in the absence of inotropic drugs, not due to hypovolemia
- Decreased cardiac index (\leq 2.2 l/min/m²)
- Signs of systemic hypoperfusion (e.g., confusion, pallor, sweating).

6. **POST-MYOCARDIAL INFARCTION:** Period of time from 12 hours after onset of infarction through day 28 (inclusive).

Post-infarction angina is considered to be the presence of anginal symptoms in the post-infarction period.

7. **STRESS TEST:** Includes any of the following tests for the detection of myocardial ischemia:

- Conventional exercise stress test
- Thallium scintigraphy (exercise or with dipyridamole) or MIBI-Tc99 or similar
- Stress echocardiography (exercise, dipyridamole, or dobutamine)
- Radionuclide ventriculography (exercise or dipyridamole).

a) CONVENTIONAL EXERCISE STRESS TEST

1) Considered **very positive** if any of the following are present:

- During the first 3 minutes of the test (or onset at heart rate less than 120 beats/minute (off beta blockers) or less than 6.5 METS) the patient develops: a) 1 mm or more of horizontal or downsloping ST segment depression that is present 80 msec after the J-point, or b) typical angina; or
- A decrease in systolic blood pressure of 20 mm mercury or more, at any time during the test; or
- More than 2 mm of horizontal or downsloping ST depression, at any time during the test; or
- Persistence of ST depression greater than 6 minutes post-exercise; or
- Test stopped at any time because of fall in blood pressure.

2) Considered **moderately positive** if not very positive, and the patient develops either of the following after the first 3 minutes of the test:

- 1 mm or more of horizontal or downsloping ST segment depression that is present 80 msec

after the J-point; or

- Typical angina.

3) Considered **indeterminate** in the absence of a very positive or moderately positive test and all of the following:

- The patient fails to reach at least 85% of the predicted maximum heart rate; and
- Heart rate-blood pressure product (heart rate x systolic arterial pressure) is less than 25,000; and
- The patient does not reach 10 METS; and
- The patient did not complete Stage IV.

4) Considered **negative** if not very positive or moderately positive and one of the following:

- Target heart rate achieved; or
- Heart rate-blood pressure product (heart rate x systolic arterial pressure) greater than 25,000; or
- At least 10 METS achieved; or
- Completed Stage IV.

b) THALLIUM SCINTIGRAPHY (EXERCISE OR DIPYRIDAMOLE)

1) Considered **very positive** if any of the following are present:

- Larger anterior wall defect; or
- Multiple reversible (partial or complete) thallium distribution in more than one arterial region during exercise; or
- Abnormal distribution associated with increased lung uptake in the absence of severely depressed left ventricular function at rest (ejection fraction < 35%).

2) Considered **moderately positive** if not very positive and:

- Reversible thallium distribution in one arterial territory.

3) Considered **indeterminate** if not very positive or moderately positive and one of the following:

- Non-reversible (persistent) thallium distribution); or
- Abnormal distribution associated with increased lung uptake in the presence of severely depressed left ventricular function at rest (ejection fraction < 35%).

4) Considered **negative** if not very positive, moderately positive, or indeterminate.

c) STRESS ECHOCARDIOGRAPHY (EXERCISE, DIPYRIDAMOLE OR DOBUTAMINE)

1) Considered **very positive** when any of the following are present:

- More than 2 areas of dyskinesia/hypokinesia on exercise; or
- Large anterior area of dyskinesia/hypokinesia on exercise.

2) Considered **moderately positive** if not very positive and one of the following:

- Exercise-induced new wall motion abnormality ; or
- Exercise-induced worsening of wall motion abnormality (e.g., a patient has hypokinesia at rest and develops akinesia or dyskinesia); or
- Abnormal ejection fraction response to exercise (absolute decrease in ejection fraction greater than 5%).

3) Considered **indeterminate** if not very positive or moderately positive and one of the following:

- Resting wall motion abnormality only; or
- Ejection fraction increases by less than 5% or decreases by less than 5% with exercise.

4) Considered **negative** if all of the following are present:

- Ejection fraction increases by more than 5%, and
- No exercise-induced wall motion abnormality, and
- Normal resting echocardiogram.

d) RADIONUCLIDE VENTRICULOGRAPHY (EXERCISE OR DIPYRIDAMOLE)

- 1) Considered **very positive** if any of the following are present:
 - Fall in left ventricular fraction of greater than 15% during exercise; or
 - Multiple induced areas of hypokinesia/akinesia.
- 2) Considered **moderately positive** if not very positive and one of the following:
 - Fall in left ventricular fraction of greater than 5% and less than 15% during exercise; or
 - Left ventricular fraction is less than 50% during exercise; or
 - Exercise-induced wall motion abnormality not present at rest; or
 - Exercise-induced worsening of a wall motion abnormality (e.g., a patient has hypokinesia at rest and develops akinesia or dyskinesia).
- 3) Considered **indeterminate** if not very positive or moderately positive and one of the following:
 - Resting wall motion abnormality only; or
 - Decrease in left ventricular ejection by 5% or less with exercise; or
 - Resting ejection fraction less than 50%.
- 4) Considered **negative** if not very positive, moderately positive, or indeterminate.

8. SURGICAL RISK LEVELS

Low/Moderate risk: Patients with a low operative risk have few or no risk factors. Their operative mortality is not significantly high and their modified Parsonnet score is less than 9. Those with a moderate risk have an expected mortality rate 2 to 4 times that of low risk patients and their modified Parsonnet score is between 9 and 18.

High risk: Patients with a high operative risk have an expected operative mortality more than 4 times that of low risk patients and their modified Parsonnet score is higher than 18.

MODIFIED PARSONNET SCALE (Table 3)

Table 3

Variable	Points
Female gender	1
Morbid obesity ($\geq 1.5 \times$ ideal weight)	3
Diabetes, type I or II	3
Hypertension (systolic BP > 140 mmHg)	3
Age:	
• 70-74 years	7
• 75-79 years	12
• > 80 years	20
Reoperation:	
• First	5
• Second	10
Preoperative intra-aortic balloon pump	2
Left ventricular aneurysm	5
Dialysis (peritoneal or hemodialysis)	10
Catastrophic states (acute structural defect, cardiogenic shock, acute renal failure)	10 to 50
Other rare circumstances (paraplegia, pacemaker dependency, congenital heart disease in adult, severe asthma)	2 to 10
Valve surgery:	
• Mitral	5
• Mitral and pulmonary artery pressure ≥ 60 mmHg	8
• Aortic	5
• Aortic and pressure gradient > 120 mmHg	7
Coronary artery bypass graft (CABG) at the time of valve surgery	2
Chronic obstructive pulmonary disease (COPD) requiring medication	4
Peripheral vascular disease with claudication	3
Previous surgery for peripheral vascular disease	3
Symptomatic carotid disease (endarterectomy, TIA, RIND, stroke)	4

Table 3

9. OPERATIONAL DEFINITION OF STENOSIS

- a) **Left main disease:** Reduction in the luminal diameter of the left main coronary artery of

- 50% or greater by visual inspection or formal calibration of angiographic findings.
- b) **Three vessel disease**: Reduction in the luminal diameter of all three major coronary arteries of 50% or greater by visual inspection or calibration of angiographic findings. If measured by visual inspection, at least one vessel must have a 70% stenosis.
- c) **Two vessel disease**: Reduction in the luminal diameter of two major coronary arteries of 50% or greater by visual inspection or calibration of angiographic findings. If measured by visual inspection, at least one vessel must have a 70% stenosis.
- d) **One vessel disease**: Reduction in the luminal diameter of one major coronary artery of 70% or greater by visual inspection or 50% by calibration.
- e) **Proximal left anterior descending (PLAD) artery involvement**: Reduction in luminal diameter of PLAD by 70% or greater on visual inspection or 50% by calibration. The PLAD refers to the portion of the left anterior descending artery that is proximal to the first septal perforator.

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