

# Appropriateness of coronary revascularization for patients with chronic stable angina or following an acute myocardial infarction: multinational versus Dutch criteria

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## Abstract

**Objective.** We convened a multinational panel to develop appropriateness criteria for percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG). To assess the applicability of these criteria, we applied them to patients referred for coronary revascularization. Finally, to understand how multinational criteria may differ from criteria developed by a panel of physicians from one country, we compared the appropriateness ratings using the multinational panel's criteria and those made using similar criteria previously developed by a panel of Dutch physicians.

**Methods.** We conducted a prospective survey and review of the medical records of 2363 consecutive patients presenting with chronic stable angina or following a myocardial infarction who were referred for PTCA ( $n=1137$ ) or CABG ( $n=1226$ ) at ten Dutch hospitals performing coronary revascularization. Appropriateness was measured using two sets of criteria developed by: (1) a Dutch panel of cardiologists and cardiothoracic surgeons in 1991; and (2) a similarly composed European panel in 1998.

**Results.** More PTCA referrals were rated inappropriate by Dutch criteria compared with multinational criteria among both patients with chronic stable angina (34.8 versus 6.1%;  $P<0.001$ ) and those with a recent myocardial infarction (28.1 versus 0.9%;  $P<0.001$ ). Among those patients referred for bypass surgery, the Dutch criteria judged a greater proportion of cases inappropriate than multinational criteria did for patients with chronic stable angina (3.7 versus 1.5%,  $P<0.001$ ). The proportion of cases rated inappropriate for bypass surgery among patients following a myocardial infarction was similar between the two panels (3.9 versus 2.4%, respectively;  $P=0.40$ ). After reclassifying the data for two of the clinical factors used in the appropriateness criteria (lesion morphology and intensity of medical therapy) based on evidence that appeared in the literature after the Dutch panel met, we found no significant differences between the Dutch and multinational panels' appropriateness ratings.

**Conclusions.** While fewer cases were judged inappropriate using the multinational criteria compared with the Dutch criteria, the differences in ratings were related primarily to the clinical factors used by each panel. These findings support the review of appropriateness criteria, and other forms of clinical guidelines, to ensure that they are current with the clinical evidence before using them to assess clinical care. Developing such criteria using a multinational panel, in contrast to multiple single country panels, would be a more efficient use of resources.

**Keywords:** coronary angioplasty, coronary artery bypass graft surgery, Europe, health policy, percutaneous transluminal, practice patterns, quality

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Patients with coronary artery disease are at risk for future cardiac events, including myocardial infarction and death. These patients may be treated with medical therapy or coronary revascularization, depending on the severity of their underlying disease, available resources, and patient and physician preferences. Yet, there are significant variations in how these patients are treated [1]. One approach to studying these variations is to examine how appropriately these patients are being managed. A number of such studies have been conducted over the past decade, but the criteria they have used to measure appropriateness were developed by a panel of physicians from the country in which the care was provided [1–6]. Using such criteria to compare care across countries is difficult. Merely comparing the rate of appropriate use of a procedure in one country with the rate in another country can often be misleading, if not incorrect [7,8].

This issue takes on greater importance as one considers the move toward greater socioeconomic integration across Europe. Although the European Union is not currently allowed to draft common medical policies for member countries, such policies may be developed in the future. To examine the feasibility of developing a common set of recommendations for performing medical procedures in Western Europe we convened a panel of cardiologists and surgeons from The Netherlands, Spain, Sweden, Switzerland, and the United Kingdom to develop criteria for the appropriate use of percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG) surgery. In this report, we apply these criteria to a previously reported sample of Dutch patients who were referred for PTCA and CABG surgery, in order to assess the applicability of the criteria. We then compare the appropriateness ratings using the multinational panel's criteria and those made using similar criteria previously developed by a panel composed solely of Dutch cardiologists and cardiothoracic surgeons.

## Methods

### Appropriateness criteria

We have described elsewhere how the Dutch panel rated clinical scenarios for coronary revascularization and assigned appropriateness categories (appropriate, uncertain, inappropriate) to them [4]. The multinational panel was conducted in a similar manner [9]. In brief, we conducted a systematic review of the literature to evaluate the benefits and risks for these procedures. Based on this review, we developed a list of clinical scenarios for PTCA and CABG. The clinical scenarios were divided into 'chapters' representing the primary clinical conditions for which patients are referred for revascularization. For this report, we restrict our presentation to those patients presenting with either chronic stable angina or following a recent myocardial infarction (i.e. between one day and 30 days before the patient's coronary catheterization). Each clinical scenario was composed of a set of variables describing the patient's clinical characteristics (e.g. severity of coronary artery disease, surgical risk). Each term in the list of clinical scenarios was defined.

In The Netherlands, the panel was composed of one experienced cardiologist or cardiothoracic surgeon from each of the twelve heart centers that performed coronary revascularization in 1991. There were six interventional cardiologists and six cardiopulmonary surgeons on the panel.

The multinational panel was composed of fifteen physicians from The Netherlands, Spain, Sweden, Switzerland, and the United Kingdom. There were three representatives from each country, two cardiologists and one cardiothoracic surgeon. 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. To complete the panel, organizers of previous panels were asked to recommend other persons with prestige in their respective specialties. Two of the three panelists from The Netherlands had been on the Dutch panel.

The literature review, list of clinical scenarios, and definitions were mailed to each panelist. Both panels rated each clinical scenario for the appropriateness of PTCA compared with medical therapy, and the appropriateness of CABG compared with medical therapy on a scale of one to nine, where one meant the procedure was highly inappropriate and nine meant it was highly appropriate. An appropriate procedure was defined as one in which the expected health benefits (e.g. increased life expectancy, relief of pain, improved functional capacity) exceed the expected negative consequences (e.g. mortality, morbidity, anxiety) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost. The Dutch panel also rated their preference for CABG compared with PTCA, but those ratings are not used in this report.

Panel members completed these first-round ratings independently and returned the rating sheets. The results were tabulated and the panelists met to discuss their ratings, modify the indication structure, and rate the clinical scenarios again. During both the Dutch and multinational panel meetings the clinical scenario structures were modified slightly. The Dutch panel met in August 1991 for two days and rated the 728 clinical scenarios that were used for these analyses a second time. Thirteen of the fifteen multinational panel members met in Madrid for a day and a half in December 1998 (two panelists had unavoidable conflicts that prevented them from attending the meeting). There were two members each from Spain and Switzerland, and three members each from The Netherlands, Sweden, and the United Kingdom, with at least one cardiologist and one cardiothoracic surgeon from each country. The multinational panel rated 208 clinical scenarios that were used for these analyses.

The final appropriateness criteria were based on the panel's median rating and level of disagreement for each procedure. Clinical scenarios were judged appropriate if the median rating was from seven to nine (without disagreement); inappropriate if the median rating was from one to three (without disagreement); and uncertain if the median rating was from four to six or if the panelists disagreed on appropriateness regardless of the median. Panelists were considered to disagree when at least four panelist ratings were

in the one to three range, and at least four ratings were in the seven to nine range.

### Patient data

We applied the appropriateness criteria to data that had been prospectively collected on a consecutive sample of Dutch patients who were enrolled in DUCAT, a prospective study of the appropriateness of use of cardiovascular procedures which included ten of the heart centers that performed CABG and PTCA in The Netherlands when the study was conducted [4]. At the time of the DUCAT study, any cardiologist in The Netherlands who performed a coronary angiography on a patient and diagnosed coronary artery disease could present information about the patient to an interventional cardiologist or cardiopulmonary surgeon at one of these centers. The presentation, which could occur in person or by letter, fax, or telephone, eventually led to a recommendation in favor of CABG, PTCA, or medical treatment. Enrolment began in February 1992 and was stopped at each center as soon as one-quarter of the expected 1992 case-load of eligible patients had been included in the study. Patients who had previously had CABG or in whom CABG was to be combined with other surgery were excluded ( $n=483$ ) as the appropriateness criteria did not apply to such patients. A total of 3981 patients were enrolled in DUCAT. We excluded from this analysis 930 patients who did not present with either chronic stable angina or following an acute myocardial infarction (i.e. between one and 30 days). We also excluded patients referred for continued medical therapy ( $n=593$ ) and those for whom we could not apply both the Dutch and multinational criteria ( $n=95$ ). Our final sample included 2363 consecutive patients who presented with chronic stable angina or following an acute myocardial infarction (i.e. between one and 30 days). Complete details on data collection have been reported previously. The study was approved by the ethics committee of the University Hospital of Rotterdam [4].

### Analytical approach

The appropriateness of each decision was determined by using a computer program to apply the Dutch panel's criteria and the multinational panel's criteria to the relevant clinical data. Decisions were classified as appropriate, uncertain, or inappropriate if they corresponded to indications rated appropriate, uncertain, or inappropriate by the panel. Results are presented as percentages of group totals, with 95% confidence intervals (CIs). CIs were calculated with the normal approximation and truncated at zero and 100. To assess the level of agreement between the Dutch and multinational panel, after adjusting for agreement due to chance alone, we used Cohen's kappa. All statistical calculations were performed using STATA 6.0 (College Station, Texas).

### Results

The patients referred for angioplasty were younger than those referred for bypass surgery (mean age 59.4 versus 62.7 years;

**Table 1** Characteristics of patients referred for coronary revascularization in The Netherlands in 1992, by procedure<sup>1</sup>

Characteristics	PTCA		CABG		Total	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
Age (years)						
< 45	87	(8)	39	(3) <sup>2</sup>	126	(5)
45–54	298	(26)	191	(16)	489	(21)
55–64	363	(32)	391	(33)	754	(32)
65–74	313	(28)	464	(39)	777	(33)
≥ 75	73	(6)	107	(9)	180	(8)
Male	822	(72)	942	(77) <sup>3</sup>	1764	(75)
History of MI	364	(32)	541	(45) <sup>2</sup>	905	(39)
Diabetes mellitus	102	(9)	185	(15) <sup>2</sup>	287	(12)
Hypercholesterolemia	414	(36)	492	(40)	906	(38)
Hypertension	360	(32)	457	(37) <sup>4</sup>	817	(35)
Clinical indication						
Chronic						
stable angina	902	(79)	1020	(83) <sup>4</sup>	1922	(81)
Recent MI	235	(21)	206	(17)	441	(19)
Anatomic disease <sup>5</sup>						
Left main	4	(0.3)	209	(17) <sup>2</sup>	213	(9) <sup>2</sup>
Three vessels	105	(9)	692	(56)	797	(34)
1 or 2 vessels with PLAD	314	(28)	203	(17)	517	(22)
1 or 2 vessels without PLAD	683	(60)	115	(9)	798	(34)
Non-significant disease	31	(3)	7	(0.6)	38	(2)

<sup>1</sup>PTCA, percutaneous transluminal coronary angioplasty; CABG, coronary artery bypass graft; MI, myocardial infarction; PLAD, proximal left anterior descending coronary artery stenosis.

<sup>2</sup> $P < 0.05$ .

<sup>3</sup> $P < 0.01$ .

<sup>4</sup> $P < 0.001$ .

<sup>5</sup>Significant coronary artery disease was defined as present if the patient had >50% reduction in luminal diameter of the left main stem coronary artery or at least a 70% reduction in luminal diameter of any other major coronary artery as determined by visual inspection. In all cases in which a patient had non-significant coronary artery disease the reduction in luminal diameter was 50–69%.

$P < 0.001$ ) and were less likely to have a history of a myocardial infarction (32 versus 45%;  $P < 0.001$ ) or diabetes mellitus (9 versus 15%;  $P < 0.001$ ) (see Table 1). PTCA patients were more likely to present following a recent myocardial infarction (21 versus 17%;  $P < 0.01$ ) and to have less severe coronary artery disease than those referred for bypass surgery (10 versus 73% had left main or three vessel disease, respectively;  $P < 0.001$ ). Patients referred for bypass surgery were more likely to be male (77 versus 72%;  $P < 0.05$ ).

**Table 2** Appropriateness of referral for CABG and PTCA in patients with chronic stable angina in The Netherlands by Dutch and multinational criteria

Procedure	Criteria	Appropriateness rating [% (95% CI)]		
		Inappropriate	Uncertain	Appropriate
PTCA	Dutch	34.8 (31.7–37.9)	35.6 (32.5–38.7)	29.6 (26.6–32.6)
	Multinational	6.1 (4.5–7.6)	24.1 (21.2–26.9)	69.8 (66.8–72.8)
CABG	Dutch	3.7 (2.6–4.9)	13.2 (11.1–15.3)	83.0 (80.7–85.3)
	Multinational	1.5 (0.7–2.2)	9.9 (8.1–11.7)	88.6 (86.7–90.6)

CABG, coronary artery bypass graft surgery; PTCA, percutaneous transluminal coronary angioplasty.

**Table 3** Appropriateness of referral for CABG and PTCA in patients following a recent myocardial infarction in The Netherlands by Dutch and multinational criteria

Procedure	Criteria	Appropriateness rating [% (95% CI)]		
		Inappropriate	Uncertain	Appropriate
PTCA	Dutch	28.1 (22.3–33.9)	40.9 (34.5–47.2)	31.1 (25.1–37.0)
	Multinational	0.9 (0.0–2.0)	23.8 (18.3–29.3)	75.3 (69.7–80.9)
CABG	Dutch	3.9 (1.2–6.5)	14.6 (9.7–19.4)	81.6 (76.2–86.9)
	Multinational	2.4 (0.3–4.5)	11.1 (6.8–15.5)	86.4 (81.7–91.1)

CABG, coronary artery bypass graft surgery; PTCA, percutaneous transluminal coronary angioplasty.

### Appropriateness ratings

Among patients with chronic stable angina (see Table 2), we found that significantly more were referred for angioplasties judged inappropriate by Dutch than by multinational criteria (34.8 versus 6.1%;  $P < 0.001$ ). Among those referred for bypass surgery, the overall inappropriateness rate was low, but still significantly greater by Dutch criteria compared with multinational criteria (3.7 versus 1.5%;  $P < 0.001$ ). There were significantly fewer inappropriate bypass surgery referrals compared with angioplasty referrals by both Dutch (3.7 versus 34.8%;  $P < 0.001$ ) and multinational criteria (1.5 versus 6.1%;  $P < 0.001$ ). Greater proportions of referrals for angioplasty were considered to be uncertain in appropriateness compared with bypass surgery referrals by both Dutch (35.6 versus 13.2%;  $P < 0.001$ ) and multinational criteria (24.1 versus 9.9%;  $P < 0.001$ ).

We found no significant difference in the rate of inappropriate referral for bypass surgery among patients following myocardial infarction (see Table 3) as judged by Dutch and multinational criteria (3.9 versus 2.4%;  $P = 0.40$ ). However, the inappropriate referral rate for angioplasty was much higher by Dutch criteria compared with multinational criteria (28.1 versus 0.9%;  $P < 0.001$ ).

### Sensitivity analysis

There were two major factors included in the appropriateness criteria developed by the Dutch panel that were not used by

the multinational panel: (1) vessel morphology; and (2) intensity of medical therapy. Vessel morphology was defined using the Type A, B, or C classification system present in 1992 when the data were collected [10]. It was designed to classify patients with respect to the probability of their undergoing a successful PTCA, with success rates decreasing as one went from a Type A lesion to a Type C lesion. Patients were considered to be on maximal medical therapy if they were prescribed a beta-blocker, a calcium channel blocker, and a long-acting nitrate (unless there were specific contraindications). We have previously shown that these factors were significant contributors to the high rate of inappropriateness found by Dutch criteria [4].

However, since the Dutch panel met, it has been shown to be extremely difficult to classify the probability of procedural success rates based solely on vessel morphology [11]. Thus, the American College of Cardiology/American Heart Association (ACC/AHA) guidelines on PTCA no longer use this classification scheme and define patients as being at high risk based on several characteristics and not merely vessel morphology [12]. Similarly, there remain significant differences of opinion regarding the definition of adequate levels of medical therapy for a patient with angina, thus one may consider that physicians are using the maximum anti-anginal medications their patients can tolerate. This approach is similar to that adopted by the ACC/AHA in their guidelines for angioplasty [12] and bypass surgery [13], where intensity of medical therapy is not used in their criteria.



**Table 4** Sensitivity analysis: appropriateness of referral for CABG and PTCA in The Netherlands by Dutch and multinational criteria, with lesion morphology and intensity of medical therapy reclassified

Procedure	Criteria	Appropriateness rating [% (95% CI)]		
		Inappropriate	Uncertain	Appropriate
PTCA	Dutch	6.5 (5.1–7.9)	9.2 (7.5–10.9)	84.3 (82.1–86.4)
	Multinational	5.0 (3.7–6.3)	24.0 (21.5–26.5)	71.0 (68.3–73.6)
CABG	Dutch	2.1 (1.3–2.9)	7.6 (6.1–9.1)	90.3 (88.6–92.0)
	Multinational	1.6 (0.9–2.3)	10.1 (8.4–11.8)	88.2 (86.4–90.1)

CABG, coronary artery bypass graft surgery; PTCA, percutaneous transluminal coronary angioplasty.

**Table 5** Level of agreement between the Dutch and multinational panels on the appropriateness of referral of chronic stable angina patients for bypass surgery, with lesion morphology and intensity of medical therapy reclassified<sup>1</sup>

Multinational panel appropriateness ratings	Dutch panel appropriateness ratings		
	Appropriate	Uncertain	Inappropriate
Appropriate	875	28	1
Uncertain	44	50	7
Inappropriate	0	5	10

<sup>1</sup> $\kappa=0.57$ .

For these reasons, the multinational panel did not include either vessel morphology or intensity of medical therapy in their criteria. To analyze the impact of these factors we performed a sensitivity analysis of the Dutch appropriateness ratings. Since there were no significant differences in the proportion of cases judged inappropriate by procedure between those patients presenting with chronic stable angina and those following a myocardial infarction using Dutch criteria, we present the results for all patients undergoing each procedure. In this analysis we considered all Type C lesions as if they were type A or B and assumed that all patients were treated with adequate medical therapy (see Table 4). Following these assumptions, we found that the proportion of cases judged inappropriate by Dutch criteria decreased to levels similar to those of the multinational panel. There were no significant differences between panels in the proportion of bypass surgeries or angioplasties judged inappropriate (2.1% by Dutch criteria versus 1.6% by multinational criteria for bypass surgery,  $P=0.37$ ; 6.5 versus 5.0%, respectively, for angioplasty,  $P=0.12$ ).

While the overall ratings were similar across panels, there may still be disagreement on individual cases. We therefore compared the ratings of the two panels for each procedure. The level of agreement across panels ranged from fair ( $\kappa=0.33$ ) for patients with chronic stable angina referred for PTCA to moderate ( $\kappa=0.57$ ) for chronic stable angina patients referred for bypass surgery (see Table 5).

## Discussion

We studied the appropriateness of referring patients for PTCA and CABG in The Netherlands using criteria developed by a Dutch and a multinational European panel of physicians. Ideally, such criteria would be based on the results of randomized controlled trials. Although such trials have been used extensively to study patients with ischemic heart disease, there are insufficient data to base recommendations solely on those sources.

Several methods have been used to develop recommendations regarding the appropriateness of use of procedures, including consensus panels, decision analytical models, and the RAND method. We chose to use the RAND appropriateness method because it has been shown to have moderate to excellent levels of reproducibility across panels for coronary revascularization indications [14]. It has also been validated by showing that the panel's ratings are associated with both clinical outcomes [15] and the results of randomized controlled trials that occurred after the panel ratings were completed [16]. We used an international panel because we believe that in comparisons of care across countries one should use a common standard. In addition, we have previously shown that there were no systematic differences in appropriateness ratings among panelists of different nationalities for coronary revascularization indications [17].

Using these criteria we found that: (1) the multinational criteria could be applied to clinical data; and (2) fewer cases

were judged inappropriate using the multinational criteria than using the Dutch criteria. As we demonstrated in the sensitivity analyses, these differences in ratings were primarily related to differences in criteria used by the different panels. This analysis illustrates the problems that can occur in comparing appropriateness rates across studies without actually applying the criteria to real patients. This study also shows how the criteria evolve over time as new evidence becomes available (e.g. lesion morphology) or as clinical judgement changes (e.g. intensity of medical therapy). The differences in criteria used by the two panels thus reflect the time period in which each of those criteria were developed: 1991 for the Dutch panel and 1998 for the European multinational panel.

A more contemporaneous study, in which appropriateness criteria using the same indication structure were developed for the treatment of benign prostatic hypertrophy by two panels of urologists, one from The Netherlands and the second from Western Europe, within one year of each other, found that the appropriateness ratings were almost identical across individual indications ( $\kappa = 0.76$ ) [18].

The recent history of appropriateness studies has shown a low rate of use of, or referral for, bypass surgery judged inappropriate. These studies have also shown that as the proportion of patients with left main or three-vessel coronary artery disease increases, more bypass surgeries were judged appropriate and fewer inappropriate [2,4,6,7,19–21]. In contrast, a substantial number of angioplasties or referrals for this procedure have been judged uncertain in appropriateness. The reason for this is most likely to be related to the evidence in the literature on the benefits of revascularization and the characteristics of the patients referred for these procedures. Seventy-three percent of the patients undergoing bypass surgery in this report had left main or three-vessel coronary artery disease, conditions for which randomized controlled trials and observational databases have shown a clear survival benefit for surgery [22]. Conversely, three-fifths of the PTCA patients presented with one- or two-vessel coronary artery disease not involving the proximal left anterior descending artery, a patient population that has been much less intensively studied, leading to more PTCA cases being rated uncertain in appropriateness.

Ideally, these criteria would be used to compare care received by patients in different countries. In order to conduct such a study, there are several conditions that must be met. These conditions include: (1) the availability of up-to-date criteria to judge the appropriateness of use of the procedures; (2) the availability of similar clinical data from each country to which the appropriateness criteria can be applied; and (3) the willingness of the investigators to present the findings even if their own country has a relatively high inappropriate rate. In fact, the original analyses for this paper included such a comparison of care in two European countries. However, after review of the final analyses showed a significantly higher inappropriate rate for one of the countries, the co-investigators from that country asked that their data be removed from the report. Thus these findings may be perceived as threatening by some physicians.

There are several limitations to this study. Firstly, as already

noted, the Dutch criteria were established in 1991 and the multinational criteria in 1998. Thus they are not comparisons of criteria developed at identical time-points. Secondly, neither the Dutch nor multinational panels included family practitioners or general practitioners; the panelists were all cardiologists or surgeons. Although previous studies have shown that specialists and generalists differ in their appropriateness ratings, the inclusion of generalists on expert panels must be based on their participation in decision-making for the procedure being rated in their respective countries. Since generalists are not involved in decisions on revascularization in some of the European countries included in this study, they were not included on these panels. If generalists had been members of these panels, it is likely that fewer indications would have been rated appropriate [23]. Thirdly, clinical data on Dutch patients are from 1992 and the selection criteria to refer patients for coronary revascularization may have changed since the data were collected, thus our results may not represent the appropriateness of use of these procedures today. Additional studies using criteria developed by multinational and single country panels at the same time and applied to data from more than one country could provide more insight into these issues.

We hope that multinational criteria such as those used in this study will ultimately be used to examine differences in the utilization and access to care across countries. The fact that both our study, after adjusting for changes over time, and the study comparing criteria developed by a European panel and Dutch panel for benign prostatic hyperplasia found few differences in ratings lends support to the use of multinational panels. Developing appropriateness criteria with a single multinational panel, in contrast to multiple single country panels, would be a more efficient use of resources. However, further studies applying criteria developed by multinational and single country panels contemporaneously to actual cases should be performed to confirm these findings.

In addition to studies of overuse, these types of criteria may also be used to identify whether there are patients who might benefit from bypass surgery who are not being offered the procedure (i.e. if there is underuse of bypass surgery). Necessity criteria, a refinement of appropriateness criteria, may be used to identify underuse of such procedures [24]. This is an important question, especially as health care expenditures increase and budgetary limits for health care are reached.

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