

Appropriateness of the use of coronary angiography in a population of patients with ischemic heart disease

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Coronary angiography;
Ischemic heart disease.

Background. Due to its pivotal role in the management of patients with ischemic heart disease, the use of coronary angiography has been continuously and progressively increasing over the years. However, an inappropriate rate of its utilization has been reported in 2 to 58% of cases. The aim of our study was therefore to evaluate the appropriateness of the indications for coronary angiography at our Institution.

Methods. All the patients undergoing coronary angiography at the catheterization laboratory of the Maggiore Hospital in Bologna during 1999 were evaluated. By retrospectively reviewing the data forms filled in at the time of insertion of the patient on the waiting list, the indications for coronary angiography were categorized as appropriate (class I/IIa), of uncertain value (class IIb) and inappropriate (class III), according to the guidelines of the American College of Cardiology/American Heart Association. In a blind fashion to this classification, the reports of coronary angiography were also reviewed to determine, both globally and in the different clinical subsets, the prevalence of significant coronary stenoses and of angiographically normal vessels.

Results. Class I/IIa indications were found in 72% of patients, as opposed to 28% in class IIb and none in class III. In the clinical subsets of stable angina, previous myocardial infarction and out-of-hospital cardiac arrest, the appropriateness was significantly higher, ranging from 74 to 100%, compared to recent myocardial infarction (63%) and unstable angina (59%) (accounting by itself for about one half of all class IIb indications). The overall prevalence of significant coronary artery disease was 87%, while in only 3% of cases did coronary angiography reveal normal vessels.

Conclusions. In our population, the use of coronary angiography was highly appropriate and only seldom of uncertain value. The accurate noninvasive selection of patients which, in view of the limited access to the catheterization laboratory, we needed to perform before proceeding to coronary angiography probably played a major role in these results.

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Introduction

Coronary angiography currently represents the reference standard for the diagnosis and clinical decision making in patients with ischemic heart disease. Its rate of utilization has been progressively and continuously increasing over the years, so that in Italy more than 140 000 coronary angiographies were performed in 1999, with a 15% increase compared to 1998 which, in turn, had shown a 22% rise in comparison with the previous year¹.

Coronary angiography however, being an invasive technique, is associated with a definite, although small, risk of complications. In addition, it is costly, both in itself and also because it often prompts *ad hoc* interventional procedures, therefore imposing a significant economic burden on the health care system. Furthermore, due to the limitation of the resources, the current ten-

dency to widen the indications for coronary angiography causes more patients to be put on the waiting list, prolonging the time of access to adequate medical care. Thus, the decision to perform coronary angiography should be the result of sound reasoning, taking into careful consideration the anticipated clinical benefit versus the risks and costs of the procedure, especially in such an era in which resources are limited and health care expenses restrained.

The appropriateness of the use of coronary angiography, therefore, at present constitutes a critical issue. A high variability in the inappropriate rate of utilization of coronary angiography, ranging from as low as 2% to as high as 58%, has been shown in previous reports²⁻⁹. Therefore, the aim of our study was to evaluate the appropriateness of the use of coronary angiography at our Institution in patients with ischemic heart disease.

Methods

The population examined consisted of all the patients undergoing coronary angiography at the catheterization laboratory of the Maggiore Hospital in Bologna (Italy) during 1999. This Institution is a non-university 800-bed hospital, endowed with all specialties, except for Heart Surgery, and serving about 300 000 people. Over 350 patients with acute myocardial infarction (MI) are admitted every year to the Coronary Care Unit, while about another 150 patients are referred yearly for coronary angiography. At the time of our survey, the access to the catheterization laboratory was limited to 3 days per week, due to shortages in the number of beds and nursing personnel, and the average time spent by the patients on the waiting list was 5 weeks. The coronary angioplasty program was provided only on an elective basis with an average waiting time of 2 weeks.

All the data forms relative to the patients who had been submitted to coronary angiography were retrospectively reviewed. These data forms were prospectively filled out by the cardiologist in charge of the patient at the time of his/her inclusion on the waiting list and report, besides personal data, the clinical diagnosis (that is the indication for the examination), the comorbidities and cardiovascular risk factors, the results of laboratory test and instrumental examinations (ECG, chest X-ray, echocardiogram, ergometric or scintigraphic stress test, peripheral vascular examinations, etc.) and the ongoing treatment. These parameters, and especially the results of the provocative tests (to which all patients with no contraindications have to be submitted before proceeding to coronary angiography) are used in our practice both to select those patients to be referred to coronary angiography and also to establish the priority of the examination.

The patients who were submitted to coronary angiography for reasons other than ischemic heart disease were identified and excluded from further analysis. The data forms of the remaining patients were evaluated, in a blind fashion to the results of coronary angiography, in order to classify the indications for the procedure according to the guidelines for the performance of coronary angiography established by the American College of Cardiology/American Heart Association (ACC/AHA)¹⁰. This classification categorizes an indication as class I when there is evidence for and/or general agreement that the procedure is useful and effective. A class II indication is that for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of performing the procedure. When, however, the weight of evidence/opinion is in favor of the usefulness/efficacy, the indication is classified as IIa, while it is classified as IIb when the usefulness/efficacy is less well established. Finally, an indication is included in class III when there is evidence and/or general agreement that the procedure is not use-

ful/effective and in some cases may even be harmful. In brief, indications for coronary angiography were categorized as class I/IIa¹⁰ if any of the following clinical/instrumental features were present: severe angina upon medical treatment, angina unresponsive to adequate medical therapy, high-risk findings (severe rest or exercise left ventricular dysfunction, multiple moderate stress-induced perfusion defects, large fixed perfusion defects with left ventricular dilation or increased lung uptake, high-risk treadmill score) on non-invasive evaluation, inability of risk stratification by means other than coronary angiography, unstable angina at a high or intermediate risk of an adverse outcome (prolonged chest pain, angina with hemodynamic impairment, chest pain at rest with dynamic ST/T wave changes, angina with hypotension, age > 65 years), suspected Prinzmetal angina, early recurrence of angina after percutaneous or surgical revascularization, MI (either Q or non-Q wave) complicated by ischemic (either spontaneous or provoked), mechanical or hemodynamic sequelae, MI (either Q or non-Q wave) with a reduced left ventricular ejection fraction and malignant ventricular arrhythmias. Indications were categorized as class IIb¹⁰ in case of: effort angina with no high-risk criteria at non-invasive testing, unstable angina with a low short-term risk (new-onset angina, a normal or unchanged ECG, increased frequency, severity or duration of chest pain) and no high-risk findings at subsequent noninvasive testing, asymptomatic post-revascularization patients with inducible ischemia but without high-risk findings at non-invasive evaluation, non-Q wave MI, MI (either Q or non-Q wave) with recurrent malignant ventricular arrhythmias without evidence of ongoing ischemia, MI (either Q or non-Q wave) with inducible ischemia at high levels of exercise, MI (either Q or non-Q wave) with the need to return to an unusually active form of employment, use in post-MI patients to find an occluded artery to be recanalized (open artery hypothesis) and perioperative MI after non-cardiac surgery. Finally, indications were categorized as class III¹⁰ if any of the following findings were present: presence of angina, but refusal of or non suitability for revascularization, even though it might be appropriate, no evidence of ischemia after revascularization, use as a screening test in asymptomatic patients, recurrent chest discomfort without objective signs of ischemia and a normal coronary angiogram during the previous 5 years.

For our purposes, the indications included in classes I and IIa were considered to be appropriate, those included in class IIb were considered as uncertain, and those included in class III were defined as inappropriate.

All the coronary angiography reports of the patients with ischemic heart disease were then retrospectively reviewed by an investigator who was blinded to the assigned categorization of the indications, in order to identify, both globally and for each of the in-

dividual ACC/AHA classes, the prevalence and extension of significant coronary artery disease. For the purposes of our study, a $\geq 70\%$ diameter narrowing of an epicardial coronary artery, and a $\geq 50\%$ diameter narrowing of the left main coronary artery, was considered as significant. Patients with angiographically normal coronary vessels were also identified since the prevalence of this pattern is commonly considered an index of appropriateness. Subsequently, the patients were further classified as one, two or three-vessel disease on the basis of the presence of significant stenoses in the territory of either one, two or three of the major coronary branches. A patient with a significant left main stenosis was considered as two-vessel disease.

Statistical analysis. Continuous variables are expressed as mean \pm SD. The differences in distribution across the categories were evaluated by means of the χ^2 statistics for unweighted contingency tables. A p value of < 0.05 was considered statistically significant.

Results

During 1999, 460 consecutive patients (367 males, 93 females, mean age 66.7 ± 7.3 years) underwent coronary angiography at the catheterization laboratory of the Maggiore Hospital in Bologna. In 421 patients (91%) the indication for the examination was represented by ischemic heart disease. Among the 39 remaining patients, mitral valve disease was the indication in 13 (3%), aortic valve disease in 14 (3%), and dilated cardiomyopathy in 12 (3%) (Tab. I).

Table I. Characteristics of the patients undergoing coronary angiography at the catheterization laboratory of the Maggiore Hospital in 1999.

<i>Overall</i>	
Number	460
Male/female	367/93
Mean age (years)	66.7 ± 7.3
Indications	
Ischemic heart disease	421 (91%)
Mitral valve disease	13 (3%)
Aortic valve disease	14 (3%)
Dilated cardiomyopathy	12 (3%)
<i>Patients with ischemic heart disease</i>	
Number	421
Male/Female	347/74
Mean age (years)	62.4 ± 8.7
Indications	
Stable angina	133 (31.5%)
Unstable angina	135 (32%)
Previous MI	133 (31.5%)
Recent MI	16 (4%)
Out-of-hospital cardiac arrest	4 (1%)

MI = myocardial infarction.

Among the 421 patients (347 males, 74 females, mean age 62.4 ± 8.7 years) in whom the indication for coronary angiography was ischemic heart disease, stable effort angina, unstable angina and previous MI accounted for about one third of cases each (133, 135 and 133 patients respectively); recent MI (that is, having occurred within the two weeks before the examination) and out-of-hospital cardiac arrest were the indication in 4% (16 patients) and 1% (4 patients) of cases, respectively (Tab. I). No patient with acute MI was present in our population since coronary angioplasty was performed only on an elective basis.

Overall, the indications for coronary angiography were appropriate, that is included in class I/IIa, in 303 cases (72%) (Fig. 1). More in detail, in 268 patients (64%) the indication was categorized as class I and in 35 (8%) as class IIa (Fig. 1). In 118 patients (28%) the indication for coronary angiography was considered as uncertain, that is included in class IIb (Fig. 1). There were no cases of inappropriate, that is pertaining to class III, indications. By examining the appropriateness of coronary angiography in the individual clinical subsets of ischemic heart disease, class I/IIa indications were found in 99 patients (74%) with stable effort angina, in 80 patients (59%) with unstable angina, in 10 patients (63%) with a recent MI, in 110 patients (83%) with a previous MI and in 4 patients (100%) with an out-of-hospital cardiac arrest (Fig. 2) ($p < 0.05$). Conversely, about one-half (47%) of class IIb indications was accounted for by unstable angina (55 patients), as opposed to 29% by stable effort angina (34 patients), 19% by previous MI (23 patients) and 5% by recent MI (6 patients) ($p < 0.05$) (Fig. 3).

Overall, significant coronary artery disease was found at angiography in 368 patients (87%), namely in 287 patients (95%) with class I/IIa indications and in 81 (69%) with class IIb indications ($p < 0.05$). The overall prevalence of one, two and three-vessel disease was 51% (187 patients), 33% (123 patients) and 16% (58 patients), respectively. One-vessel disease was present in 126 patients (42%) with class I/IIa indications and in 61 (52%)

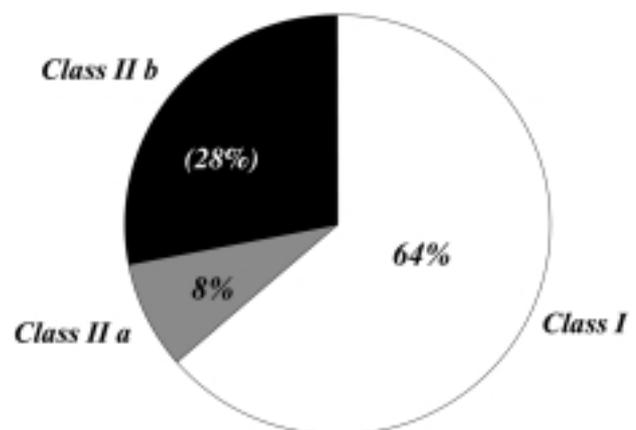


Figure 1. Overall distribution of the classes of indications.

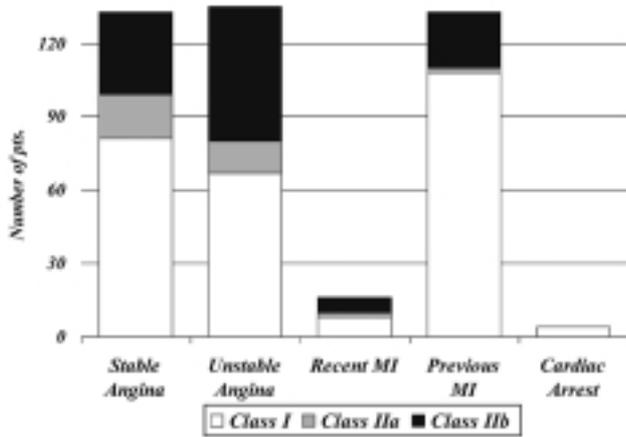


Figure 2. Distribution of the classes of indications in the different clinical subsets. MI = myocardial infarction.

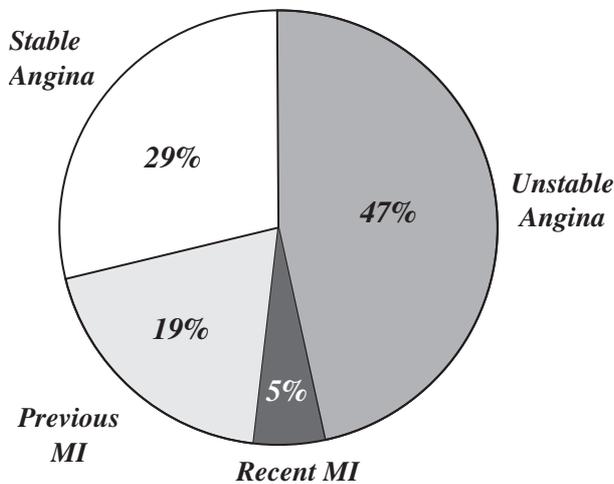


Figure 3. Distribution of the different clinical subsets in the class IIb group of indications. MI = myocardial infarction.

patients with class IIb indications ($p < 0.05$) (Tab. II). Two-vessel disease was found in 107 patients (35%) with class I/IIa indications and in 16 (14%) patients with class IIb indications ($p < 0.05$) (Tab. II). Three-vessel disease was present in 54 patients (18%) with class I/IIa indications and in 4 (3%) patients with class IIb indications ($p < 0.05$) (Tab. II). Conversely, angiographically normal coronary vessels were found overall in 14 cases (3%): 5 out of 12 in the class I group, none in the class IIa group, and 9 out of 37 in the class IIb group ($p = NS$) (Tab. II).

Discussion

In the present era of limited resources and of the need for restricted health care expenses, an adequate rationale in the use of coronary angiography appears highly advisable. However, due to its pivotal role in the diagnosis and management of ischemic heart disease, its use has been continuously and progressively growing. However, a 2 to 58% rate of inappropriate use of coronary angiography, defined according to various criteria, either developed by a consensus or expert panel or by the RAND investigators (including both specialists and generalists)¹¹, was reported in previous studies²⁻⁹. In New York State coronary angiography was found to be appropriate in 76% of cases, of uncertain value in 20% and inappropriate in 4%². When comparing the use of coronary angiography in Canada and New York State, the rate of appropriateness was found to be 77 and 58% respectively using the (more restrictive) Canadian criteria, and 58 and 51% respectively using the US criteria³. On the other hand, in Canada and New York State the indications were rated inappropriate in 9 and 10% of cases respectively, according to the Canadian criteria, and in 5 and 4% of cases respectively using the US criteria³. In another comparison between Canada and the United States, coronary angiography was used inappropriately in 9% and in 15-18% of cases respectively⁴. In two Israeli hospitals the inappropriateness rate was 58%⁵, while it ranged from 10 to 28% in three centers in England⁶. In a population of Swedish patients with stable angina queuing for coronary angiography, the examination was classified appropriate in 89% of cases, of uncertain value in 9%, and inappropriate in 2%⁷. Finally, other reports showed in the United States and United Kingdom rates of appropriateness and of inappropriateness ranging from 49 to 77% and from 17 to 21%, respectively^{8,9}.

In our population, the utilization of coronary angiography was found to be highly appropriate, as demonstrated by the high prevalence of class I/IIa indications, the absence of class III indications, the high prevalence of significant coronary stenoses and the very low prevalence (much lower than the 10% requested by the ANMCO-SIC Commission in order to define the activity of a catheterization laboratory as appropriate)¹² of angiographically normal coronary vessels. Besides the fact that for the categorization of the indications we used criteria which were different from

Table II. Prevalence of coronary artery disease in the different classes of indications.

	1 VD	2 VD	3 VD	Angiographically normal
Class I	110 (41%)	97 (36%)	49 (18%)	5 (2%)
Class IIa	16 (46%)	10 (29%)	5 (14%)	0
Class IIb	61 (52%)	16 (14%)	4 (3%)	9 (8%)

VD = vessel disease.

those employed in other studies reported in the literature²⁻⁹, the most likely explanation of our results is the limited access to the catheterization laboratory we had during the period of our survey. In almost all patients in fact, unequivocal symptoms and/or strong positivity of some kind of functional test, were requested before proceeding to coronary angiography. On the other hand, in patients with stable angina pectoris, this strategy was shown to be actually associated with a significantly higher appropriateness rate. In those patients at high risk who had previously undergone myocardial scintigraphy, the revascularization rate was in fact 16% compared to 30% in those who were not studied by means of functional tests¹³. Accordingly, about two thirds of our population consisted of patients with stable angina pectoris, either with or without a previous MI, for whom, on the basis of the clinical course and of the results of stress tests, the guidelines for the performance of coronary angiography quite clearly address the strategy to be followed¹⁰. Similarly, coronary angiography is considered mandatory in patients resuscitated from out-of-hospital cardiac arrest, known to be commonly related to ischemic heart disease¹⁰. In these latter three groups of our patients in fact, the overall appropriateness rate of coronary angiography was, on average, 86% (range 74-100%). Even for patients with a recent acute MI, there is little controversy about the decision to perform coronary angiography, since the early demonstration of residual ischemia and/or the occurrence of complications represent well accepted indications¹⁰. However, in the attempt to revascularize a persistently occluded infarct-related artery or in order to stratify patients with a non-Q wave MI, some favor a more aggressive approach, even if a definitive demonstration of its usefulness is lacking. Accordingly, with regard to our patients with a recent MI, in 37% of cases the indication to coronary angiography during the hospital-management phase was rated of uncertain value. Even less defined is the need for and the timing of coronary angiography in patients with unstable angina pectoris, for whom the issue of an early versus a delayed aggressive approach seems to necessitate further clarification. Consistent with that, are both the lowest appropriateness rate found in our patients with unstable angina (accounting for about one third of the entire population) and the highest prevalence of this clinical subset within the group with class IIb indications. It is to be noted, however, that our categorization was performed according to the ACC/AHA guidelines which were released in May 1999¹⁰, that is before the results of the FRISC II study were made available¹⁴. Since this study proved the superiority, in acute coronary syndromes, of an early invasive strategy, it may be that some indications we have rated uncertain, could on the other hand be considered appropriate.

Study limitations. Two main limitations have to be taken into account when considering our results. First,

the retrospective nature of the analysis we performed could somehow have weakened the validity of our findings, even owing to the fact that in several cases proper matching of the clinical diagnosis with the corresponding guideline recommendations was all but obvious. Second, we did not evaluate the number of patients who may have needed coronary angiography and did not have it nor the number of those who were re-hospitalized after having been discharged without a coronary angiogram, although these parameters are recognized as important indices of appropriateness. However, due to the fact that part of the patients were referred to our catheterization laboratory from other departments, hospitals and office cardiologists, such an analysis could not be properly carried out. In fact, we were not aware of the different patient subsets encountered in these different places nor could we regularly track the fate of the patients after having referred them back to the forwarding centers.

Conclusions. Rationalization of the use of coronary angiography appears to be achievable in common clinical practice. The accurate non-invasive triage of patients to be referred for coronary angiography is probably the most important variable in assuring both a high rate of appropriateness and a low rate of inappropriateness. It would be of interest, however, to evaluate how coronary angiography is used in centers with unrestricted access to the catheterization laboratory and with an emergency coronary angioplasty program. Although the use of the ACC/AHA classes of indications appears feasible and useful, even the time spent by patients on the waiting list should probably be taken into account for such an evaluation. While prolonged in-hospital stay due to restrictions in the availability of invasive facilities increases the costs of medical care, waiting for coronary angiography has been shown to carry a significant risk of cardiac events in outpatients¹⁵. Coronary angiography, therefore, should be delivered not only appropriately, but also within the appropriate time. Monitoring both these parameters should help in trying to reconcile the issue of the regionalization of invasive cardiac procedures (which provides a higher quality of care) with that of the proliferation of catheterization laboratories (which allows a more rapid access to medical care).

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