European Heart Journal (1999) **20,** 1261–1270
Article No. euhj.1998.1307, available online at http://www.idealibrary.com on IDEAL®

Audit and quality control in angioplasty in Europe: procedural results of the AQUA Study 1997

Assessment of 250 randomly selected coronary interventions performed in 25 centres of five European Countries

W. Maier, M. F. Enderlin, T. Bonzel, N. Danchin, G. Heyndrickx, V. Mühlberger, K. L. Neuhaus, F. Piscione, N. Reifart, J. Antoni, Y. Ogurol, M. B. Wischnewsky and B. Meier on behalf of the AQUA Study Group, Nucleus Clinical Issues, Working Group Coronary Circulation, of the European Society of Cardiology

Department of Cardioloy, University Hospital, Bern Switzerland and Centre for Computing Technology, University of Bremen, Germany

Aims Percutaneous transluminal coronary angioplasty (PTCA) has become the most widely used major intervention in western medicine. However, there is disparate use of this technique among different European countries and the U.S.A. In an attempt at quality assurance, the working group Coronary Circulation of the European Society of Cardiology has carried out a study on appropriateness, necessity, and performance of PTCA in Europe. The present paper reports on the procedural results of this survey.

Methods From the countries participating in the European Registry of Coronary Intervention, the three countries with the highest absolute PTCA volume (Germany, France, and the United Kingdom) and two randomly selected countries (Belgium and Italy) were chosen for investigation. In these countries, five centres were selected at random according to the following criteria: one centre with >1000, three centres with 300–1000, and one centre with <300 procedures per year. In each of these, 10 cases from the first half of 1997 were randomly identified and all pertinent documentation was collected.

Results In 250 cases, 325 stenoses were addressed as target lesions. Single vessel disease was present in 41%. History included stable angina in 49%, unstable angina in 32%, atypical chest pain in 6%, no anginal pain in 12%, and acute/subacute myocardial infarction in 13%. The percentage of patients with either positive stress test and/or unstable angina, acute/subacute infarction, previous infarction (within 6 months) or coronary revascularization amounted to 98%. Single vessel intervention accounted for 90%. In 41% balloon-only angioplasty was performed and in 54% at least one stent was implanted with considerable variation among countries. The use of other new devices amounted to only 3%. In 92%, the operators documented a successful procedure. Major complications (myocardial infarction, emergency bypass surgery, or death) were found in 4·8%.

Conclusion Based on scrutinized hospital and operator data, the present study revealed a satisfactorily high percentage of justifiable indications, an adequate procedural success rate, and an acceptably low complication rate. Further analysis by an expert panel will address appropriateness, necessity, and procedural performance of the individual cases.
(Eur Heart J 1999; 20: 1261–1270)

Key Words: Audit, coronary angioplasty multinational European study, procedural results, PTCA, quality control.

Introduction

Percutaneous transluminal coronary angioplasty (PTCA) was introduced into clinical medicine in 1977 by Andreas Grüntzig in Zurich, Switzerland [1,2]. In the past 20 years, PTCA and related technologies have become

Revision submitted 14 September 1998, and accepted 23 September 1998.

Correspondence: Bernhard Meier, MD, Professor and Head of Cardiology, Inselspital, University Hospital, 3010 Bern, Switzerland.

0195-668X/99/171261+10 $18.00/0

© 1999 The European Society of Cardiology

the most widely used major therapeutic interventions in medicine worldwide. Two major reasons for the unique success of this medical technique may be identified. In successful cases, PTCA changes a patient from a disabled person into a physically fully functional human being overnight, with almost no suffering. The procedure is popular with patients, particularly in comparison with coronary bypass surgery, which necessitates general anaesthesia, thoracotomy, and an extended rehabilitation period. It is also popular with physicians because the medical community acknowledges that the often spectacular results of PTCA are achieved thanks to sound training, good clinical judgement, and considerable manual dexterity in a highly sophisticated and technical environment. The exponential growth of this technique, however, engenders a considerable increase in healthcare costs.

In 1992, the Working Group on Coronary Circulation of the European Society of Cardiology (ESC) instituted a registry on coronary interventions extending to all members of the ESC. Data have been published for the years 1992–1994[3–5]. In the participating European countries, more than 220 000 PTCA procedures were registered in 1994 and for the United States of America, more than 400 000 interventional procedures are currently estimated per year[6–8]. However, according to these data, there is a wide variation in the utilization of the procedure in Europe ranging from none to 1091 PTCA procedures per 1 million of population per year[5]. The utilization of PTCA in the U.S.A. was estimated at more than 1200 per million of population per year at the beginning of this decade[8]. Many factors may account for the regionally disparate use of PTCA in Europe, the most important among them being differences in the socio-economic developmental status of the different European regions, as well as purposeful steering of healthcare expenditures. However, only non-medical factors can explain the difference between 1091 coronary interventions per million inhabitants performed in Germany in 1994 and 242 in the United Kingdom. Expressed as interventions per national gross domestic product, this translates to $43/10^9$ US$ in Germany compared to $14/10^9$ US$ in the United Kingdom[9]. A general goal of the European healthcare system is equal health for all at affordable cost. Guidelines for appropriate indications for PTCA have been issued by several authorities, among them the American Heart Association/American College of Cardiology, the ESC, and several national European societies[8,10–14]. The European cardiology community must be prepared to answer the questions raised by these issues and assist the administrations in proper distribution of resources. Therefore, the Working Group on Coronary Circulation of the ESC has mandated the AQUA study (AQUA=*A*udit and *Q*uality control in *A*ngioplasty) on appropriateness (=sound indication for the procedure considering the general situation of the patient, the potential benefit, and the risk, but not the cost), necessity (=the procedure is not only appropriate but omission of it would jeopardize the health outcome of the patient to a significant degree), and performance of PTCA in randomly selected patients, institutions and countries in Europe.

Purpose

This paper presents the procedure-related data from 250 randomly selected coronary interventions from 25 centres in five European countries, regarding history, diagnostic tests, procedures performed, in-laboratory and out of laboratory complications, and outcome up to discharge.

Methods

The study was designed by the nucleus Clinical Issues of the Working Group on Coronary Circulation of the ESC. It is an attempt at quality control as a first step to quality assurance by assessing appropriateness, necessity, and procedural performance of angioplasty cases performed during the first half of 1997. The study concentrated on a small, but representative sample volume to respect the limited budget. The sampling was based on 'stratified sampling' techniques to optimize the result for the given sample volume[15]. In each of five European countries, five interventional centres were selected at random. In each centre, 10 cases were analysed.

Country, centre, and case selection

From the countries participating in the annual PTCA registry of the ESC, the three countries with the highest absolute PTCA volume according to the 1994 registry data were chosen a priori for investigation: Germany, France, and the United Kingdom. Two additional European countries were selected at random. To make sure the selection was random, the following criteria were established based on the European registry 1994:

- Number of procedures performed per million inhabitants >20% of the number of procedures in Germany (highest volume per million inhabitants)
- More then 12 interventional catheter laboratories per country to enable the selection of five centres by chance.

This yielded a random selection of the following qualifying countries: Austria, Belgium, Italy, the Netherlands, Spain, Switzerland. Under the supervision of the president of the ESC, Belgium and Italy were randomly selected. The in-country centre selection was carried out randomly by the national representatives (see below) of the working group, using the following criteria:

- 1 centre performing >1000 procedures/year (category I)

- 3 centres performing 300–1000 procedures/year (category II)
- 1 centre performing <300 procedures/year (category III)

If in the respective country one category was not available, the number of the next category was increased by one. Replacement centres were also selected, in case participation was refused.

Local case selection was by a computer randomizer, which was operated on site during the audit. The randomizer generated dates from the first half of 1997. Weekends were omitted to avoid a bias towards rescue cases. Centres were asked for the number of interventions at the selected dates. The randomizer determined one intervention (e.g. number 3 from five interventions at that date) according to the local registry. If no intervention was performed the closest date with interventions was chosen and the random selection repeated for that date.

Course of the study

The study was initiated in April 1997. A customer-designed computer program (AQUA Intervent) for data assessment was developed in cooperation with the Centre for Computing Technology, University of Bremen, Germany. After centre selection by the regional representatives, data collection started in July 1997 and was finished in October 1997.

Data collection

The identified centres were contacted, either by the local representatives or the core centre in Bern, Switzerland, and asked if they would participate. In France and Italy, all selected centres agreed to participate. In Belgium, one centre in category III refused participation. In Germany, the first centre selected in category III had discontinued interventions and the next two randomized centres refused participation. They were replaced by a random substitute of the respective category. In the United Kingdom, four centres of category II declined involvement and were replaced as described above. Eight of the 25 centres (32%) were university hospitals.

All participating centres were visited by an interventional cardiologist who performed the case selection on site and collected all pertinent source documents, interventional protocols, and image documentation of the selected procedures. When the hospital's administrative system was able to provide the material immediately, the auditor went through the documents and image material a first time on-site, together with a representative of the institution. Data were entered into a dedicated computer data bank, the AQUA Intervent program. All relevant source documents as well as films, videos, or compact disks were collected and sent to the core centre in Bern for further data analysis. Care was taken to anonymize all patient data and to assure complete back-tracing to the source documents, if necessary.

The AQUA Intervent programme

The database was designed to provide a structured overview of clinical and procedure-related data necessary for concise recognition of the case and assessment of appropriateness, necessity, and procedural performance of coronary interventions, according to the published criteria of the American Heart Association/American College of Cardiology and the ESC. Due to the retrospective characters of the study and the different styles of documentation in the respective countries, data were limited to what were regarded as essential. Figure 1 shows the architecture of the programme and Fig. 2 is a submenu; Table 1 summarizes the data categories and examples of the selected items. Technically, the programme is relational and uses the Borland-database engine. It has interfaces to statistical programs such as SPSS, or SAS, to other databases such as d-Base, or Oracle, or to spreadsheets such as Excel. Its structure allows easy and rapid adaptation (e.g. extension of the data model, multi-lingual versions) to a wide range of applications. The data fields are grouped on tabloid sheets according to the specific area of the documentation, e.g. history, diagnostics, or stenoses. As shown in Fig. 2, for stenosis selection, the coronary segments are displayed and the user enters the stenoses and target lesions by mouse click.

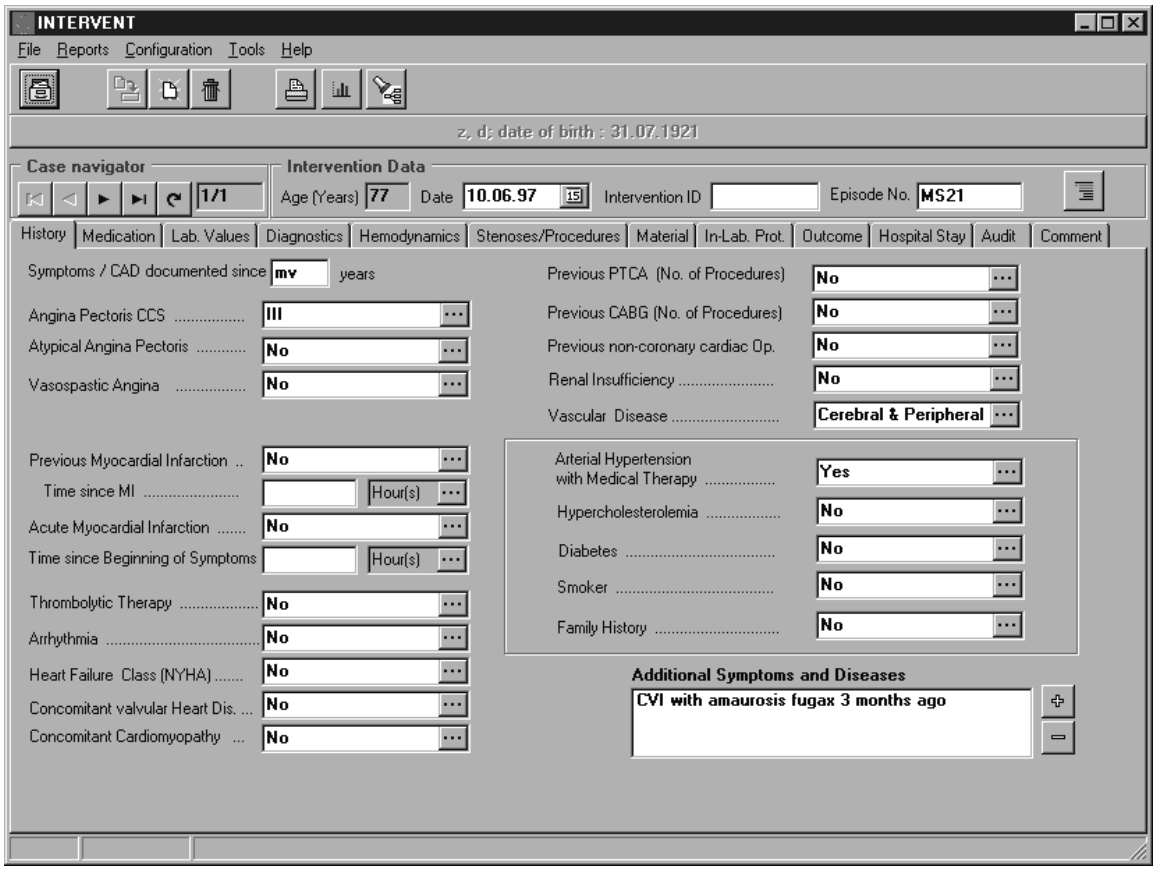
Data analysis

The present data reflect the documentation of the participating centres. This documentation was analysed and cross-checked for consistency and correspondence to image documentation. If possible, pertinent notes were recorded during the audits (e.g. nursing comments regarding minor bleeding), but deeper source document levels, such as original stress test protocols, were not generally scrutinized. Therefore, the information provided by admission and discharge letters, in-hospital notes, and procedural protocols were accepted as standard. Items of the AQUA questionnaire which could not be obtained were entered as not available, even if this information might have been present at the time of the procedure in an unreproducible form, such as oral or unretrievable written communication from the referring physician or another department/hospital.

Results

History, indications, and diagnostics

Baseline characteristics of the 250 study patients are summarized in Table 2 together with selected results.



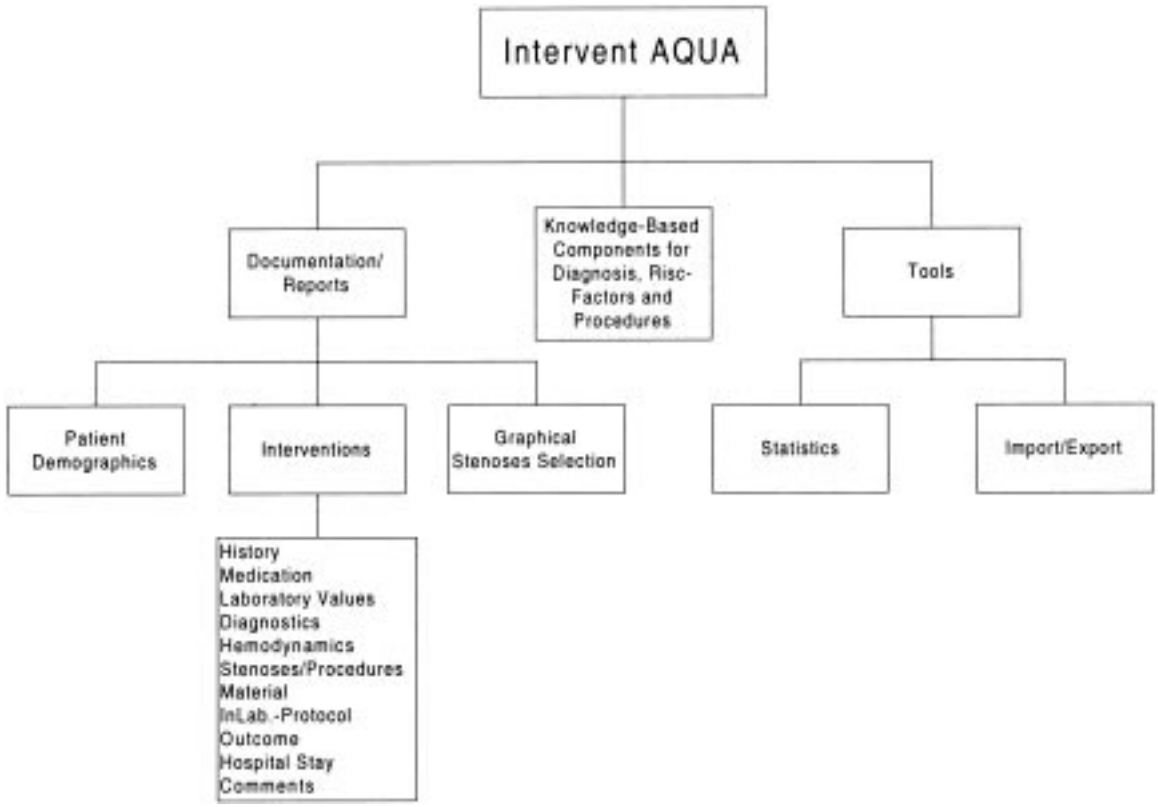


Figure 1 **The architecture of the Intervent AQUA programme.**

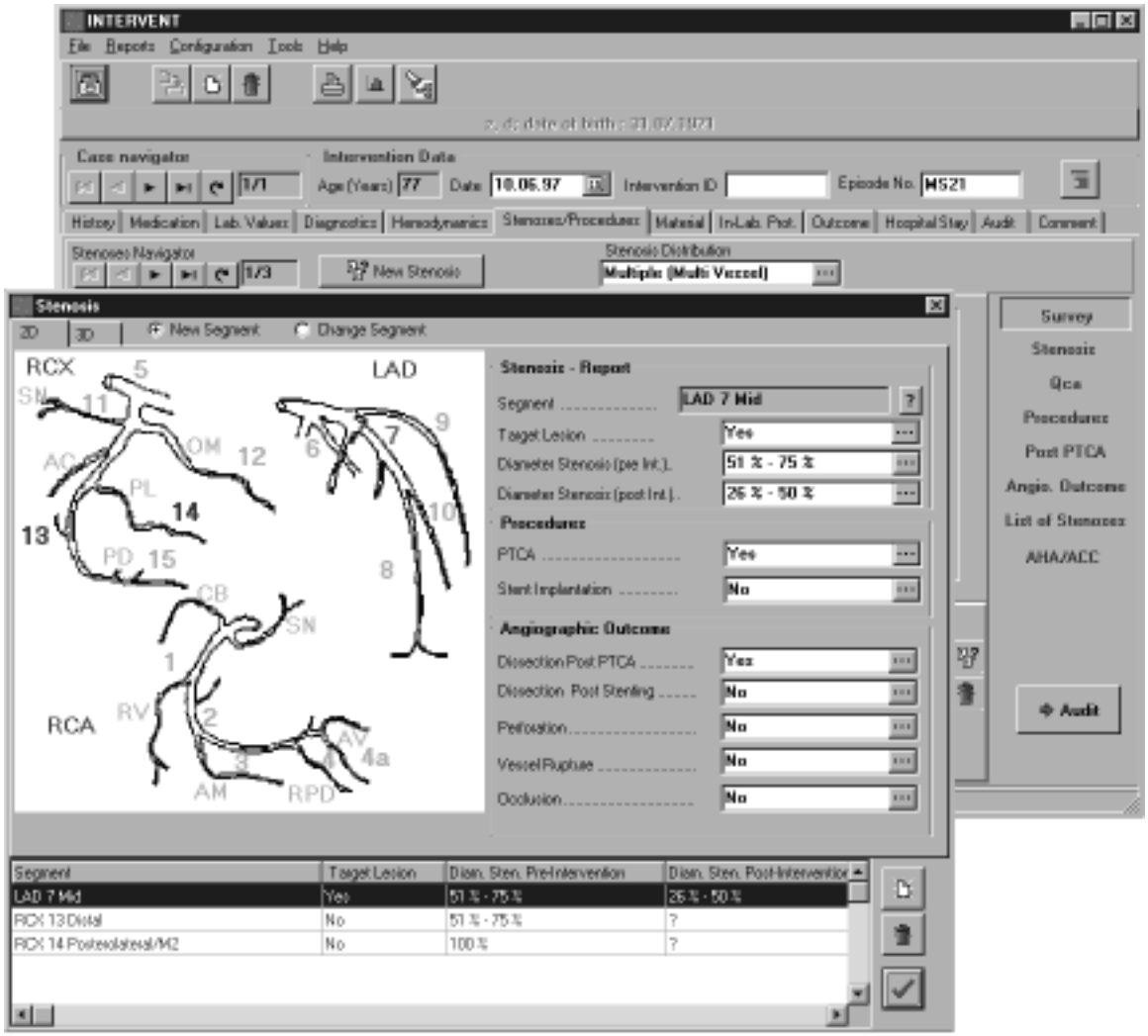


Figure 2 **The stenosis submenu.**

Table 1 Data acquisition

Category	Items
History	Previous myocardial infarctions, angina pectoris, previous PTCA, risk factors, . . .
Medication prior to intervention	Aspirin, beta-blockers, lipid lowering drugs, ACE inhibitors, vasodilators, . . .
Laboratory values	Cholesterol, HDL, LDL, triglycerides, . . .
Diagnostics	Stress tests, echocardiography, indications for diagnostic catheterization, . . .
Haemodynamics	Heart rate, blood pressure, systemic circulation, pulmonary circulation, . . .
Stenosis/Procedures	segment, diameter stenosis by visual estimate, QCA, angiographic outcome, . . .
Material	Catheters, balloons, guide wires, stents
In-laboratory protocol	Duration of procedure, radiation dose, type of contrast media, medication, . . .
Outcome	In-laboratory complications, out-of-laboratory complications, recurrent angina, mortality, . . .
Hospital stay	Duration, clinical end-points, . . .
Comments	

History prior to intervention included stable angina in 49%, unstable angina in 32% and atypical chest pain in 6%. The definition of unstable angina was chosen according to Braunwald[16]. Because of the different levels of local documentation, no attempt was made to extract the Braunwald classification of unstable angina pectoris from the provided original data. Interventions were performed in 13% for acute or subacute myocardial infarction. For the purpose of this study, acute myocardial infarction has been defined as myocardial infarction that occurred within the last 24 h prior to the audited intervention and was diagnosed by any

Table 2 Baseline characteristics

	Total	Belgium	Germany	France	Italy	U.K.
Patients (n)	250	50	50	49	51	50
Male (%)	82	84	78	82	82	86
Mean age (years)	63	64	64	64	62	60
Stable AP (%)	49	42	44	43	53	54
AP CCS IV (%)	32	36	28	37	35	24
Stress test (%)	47	50	50	39	57	40
Positive stress test (% of study population)	39	36	34	37	50	38
Acute+subacute MI (%)	13	14	24	12	8	8
MI within 6 months (%)	36	28	36	39	47	28
Previous PTCA (%)	28	32	36	25	22	28
Previous CABG (%)	12	14	10	14	5	18
Positive stress test and/or	98	96	96	98	100	100
Unstable angina						
Acute+subacute MI						
Previous MI within 6 months						
Previous intervention/CABG (%)						
Lesions>50% (n)	556	109	112	115	110	110
Target lesions (n)	325	61	65	69	64	66
Target lesions/intervention (n)	1·3	1·2	1·3	1·4	1·3	1·3
1 vessel disease (VD) %	42	42	36	39	45	50
2 and 3 VD %	58	58	64	61	55	50

AP=angina pectoris; CCS=Canadian Cardiovascular Society; MI=myocardial infarction; PTCA=percutaneous transluminal coronary angioplasty; CABG= coronary artery bypass grafting; VD=vessel disease; VI=vessel intervention; U.K.=United Kingdom.

definition according to the local policy (ECG and/or enzymatic changes fulfilling the respective institution's criteria for myocardial infarction) and subacute myocardial infarction was defined as that which occurred between 24 and 48 h prior to the selected procedure. The 24 h timing was chosen to reflect data from the Fibrinolytic Therapy Trialist Collaborative Group, which indicated a discrete, although statistically not significant advantage for the reperfusion group even between 13 and 18 h[17]. No anginal pain was reported in 12% of the study group. Of the 31 patients without anginal pain, 15 had had a previous PTCA and/or bypass surgery. Stable angina was further subclassifiable, according to the Canadian Cardiovascular Society (CCS) score[18], from I–IV in 71%, whereas in 27%, only typical angina was reported and in 2% no information was available. Stress tests of any kind (exercise ECG, myocardial scintigraphy, stress echocardiography or exercise radionuclide–ventriculography) were available in 47% of all cases, ranging from 39% in France to 57% in Italy (Table 2). The percentage of patients with either positive stress tests and/or unstable angina, acute or subacute infarction, previous myocardial infarction within the preceeding 6 months and previous coronary revascularization amounted to 98%. The indications in the remaining five patients not fulfilling these criteria were: documentation of significant stenoses at diagnostic catheterization 3 weeks before (1), stable angina CCS class III with intravenous heparin (1), pulmonary oedema as a first manifestation of coronary artery disease (1), new atypical symptoms and documentation of reduced left ventricular ejection fraction by echocardiography (1), and new symptoms classified as partially typical, partially atypical (1).

Risk factors

In 184 cases (74%), information about risk factors was available. The leading risk factor was hypercholesterolaemia in 53%, followed by hypertension in 41% and active smoking in 26%. Adding all ex-smokers to active smokers, the risk factor smoking amounted to 57% and exceeded hypercholesterolaemia. Three or more cumulated risk factors were present in 18% of patients.

Target lesions (Table 2)

In 250 cases, a total of 556 significant stenoses were documented by the operators, of which 325 were addressed as target lesions, resulting in an average of 1·3 target lesions/session. Single vessel disease was present in 43% of the patients, whereas two and more vessel disease was found in 57%. The distribution of target lesions among the principal segments is indicated in Fig. 3. Figure 4(a) and (b) show the operator's rating of target lesion severity pre- and post-intervention.

Interventions performed (Table 3)

In 47% of these cases, PTCA was performed in the same session as diagnostic angiography, whereas in 53%, a

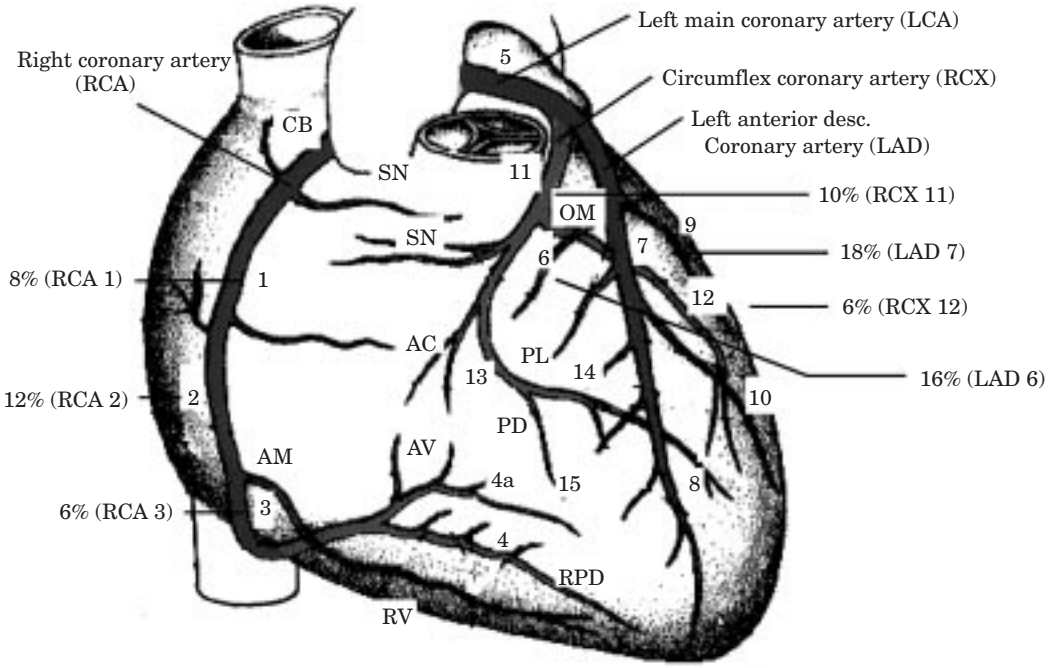


Figure 3 **Distribution of target lesions among the principal segments. Only native segments with a frequency of $\geq$5% as target lesions are indicated.**

two-step approach was pursued. Single vessel intervention amounted to 90%, two and more lesions were addressed in 10%. In 103 patients (41%), balloon-only angioplasty was performed and in 134 cases (54%) at least one stent was implanted in one target lesion with a considerable variation per country. Expressed per target lesion, in 48% of the lesions stents were implanted. Taking into account the use of stenting per intervention (not the number of stents used), an average of 63% of procedures involved stenting with a variation from 42% to 82%. In the United Kingdom, in one centre all selected patients were stented. The United Kingdom data without this centre gives an average of 57% of interventions with stents which is quite close to the average of all countries (54%). Only in eight procedures (3%) were new devices chosen (rotablator in four cases, laser wire in two cases and cutting balloon in two cases). Intravascular ultrasound as an adjunctive diagnostic tool during the intervention was used in only three cases.

Materials and procedure-related data

Data on contrast media were available in 70%. In 54% of these ionic low osmolar and in 46% non-ionic contrast medium was used. More than 400 ml of contrast medium was applied in 10% of the patients, in 33% an amount between 200 ml and 400 ml was reported.

The guiding catheter size was missing in 10% of the cases and was equally distributed between 6F (36%), 7F (32%) and 8F (32%) among those with available data.

The duration of the procedure was documented in 55%. The mean duration in those patients with combined (diagnostic and interventional) procedures was 63 min, 40% were between 30 and 60 min, 37% between 60 and 120 min and 8% took more than 2 h. In stand-alone interventions, the mean duration was 71 min, 9% were less than 30 min, 30% between 30 and 60 min, 47% between 60 and 120 min and 14% took more than 2 h.

Complications (Table 4)

Complications were listed as in-laboratory and out-of-laboratory complications. Death, procedure-related myocardial infarction (MI) and emergency bypass surgery (CABG) were considered as major complications. In-laboratory, acute occlusion and infarction occurred in 1·6%. Out-of-laboratory, acute occlusion and infarction occurred in 3·6%. Recurrent angina or unstable angina were reported in 5·2%, haemodynamic compromise in 0·8% and major bleeding in 1·6%. There was no in-laboratory death. Out-of-laboratory there was one cardiac death (0·4%) during the procedure-related hospital stay. One of the end-points death, MI, or emergency CABG was met in 4·8%. Relating all observed major and minor complications to the centre category, there was a trend towards higher complication rate in centres performing less than 300 procedures/year compared to those with more than 1000 procedures/year (12% vs 6% ns).

Discussion

The AQUA study addresses for the first time the issue of quality control in interventional cardiology in Europe.

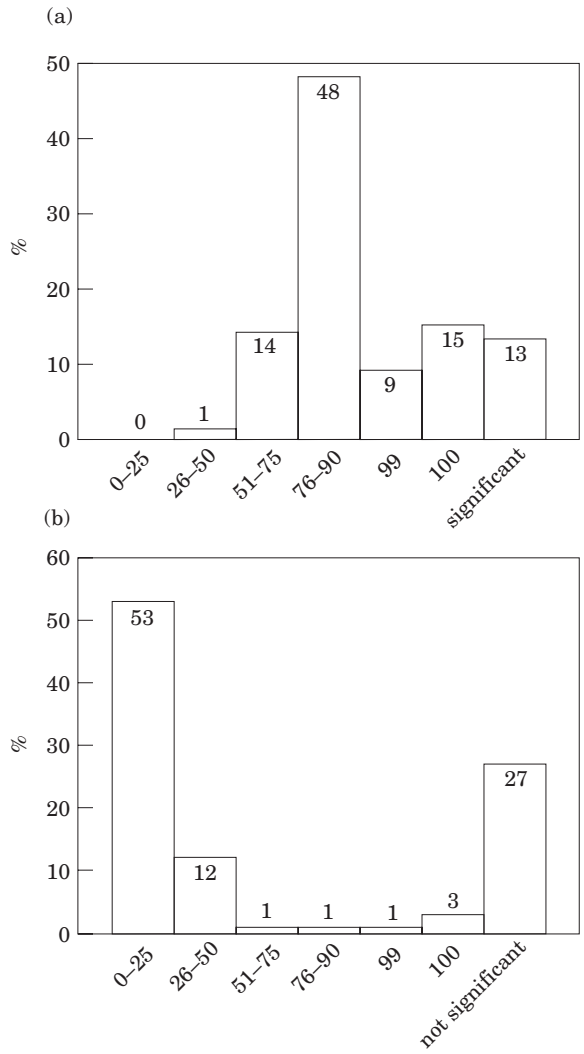


Figure 4 **(a) Frequency of the relative diameter stenosis pre-intervention (operator's rating by visual estimate); (b) frequency of the relative diameter stenosis post-intervention (operator's rating by visual estimate).**

The present data give a statistical overview of 250 randomly selected coronary interventions from five European countries. Although these data rely on operator and hospital documentation, they were individually checked at the maximal level of profoundness of the provided source documents, exceeding that of questionnaires sent out to the centres as in the European registry[3,4], or the German national registry[19]. Moreover, the procedures will be subjected to an expert panel rating, which will provide objective data on appropriateness, necessity and the procedural performance of individual cases, in addition to an assessment of operator/expert, inter-observer and intra-observer agreement.

Coronary interventions are expensive therapeutic strategies. Consequently, the question of appropriate indications is increasingly being raised. In 9% of a large German multicentre registry[20] recently, PTCA was indicated in asymptomatic patients. This was interpreted as an inappropriate indication by media and insurance companies and stimulated further discussions with regard to engendered expenditure and needless risk. However, in this European study, in 98% of cases (with very low variability throughout all countries) interventions were being performed in patients who had at least one of the following criteria: positive stress test, unstable angina, acute or subacute myocardial infarction, previous myocardial infarction within 6 months, or previous coronary revascularization. Although some of these data reflect the rating of the physicians involved (e.g. classification of angina as unstable) and others might be considered as not indicative for an intervention per se (e.g. previous myocardial infarction within 6 months or previous coronary revascularization), a relative indication for interventional therapy can be derived from these criteria, together with documentation of significant stenoses. This finding reflects the reassuringly competent level of the centres involved. On the other hand, it is possible that the planned assessment by experts, disregarding the operators' opinions, corrects

Table 3 Intervention characteristics

	Total	Belgium	Germany	France	Italy	U.K.
PTCA balloon only (% of cases)	41	50	46	37	39	32
PTCA+stenting (% of cases)	54	40	46	61	57	64
PTCA+new devices (% of cases)	3	6	2	4	0	4
Stents/target lesion (n)	0·48	0·34	0·46	0·48	0·50	0·62
Stents/interventions (%)	63	42	60	67	63	82
1 vessel intervention (VI, %)	90	96	92	84	88	90
2 and 3 VI (%)	10	4	8	16	12	10
Combined diagnostic catheterization+intervention (%)	46	56	42	36	57	40

AP=angina pectoris; CCS=Canadian Cardiovascular Society; MI=myocardial infarction; PTCA=percutaneous transluminal coronary angioplasty; CABG= coronary artery bypass grafting; VD=vessel disease; VI=vessel intervention.

Table 4 Complications

	Total	Belgium	Germany	France	Italy	U.K.
Acute occlusion in-laboratory and out of laboratory (%)	3·6	4·0	2·0	4·1	5·8	2
Procedure-related MI (%)	4·0	4·0	0	4·1	7·8	4·0
Emergency CABG (%)	0·8	2·0	2·0	0	0	0
Death (%)	0·4	0	0	0	0	2
MI, CABG, death (%)	4·8	6·0	2·0	4·1	7·8	4·0

some of the figures, modifies some of the indications, or suggests other strategies such as bypass surgery or medical therapy for individual cases.

Interventions for acute ischaemic syndromes were performed frequently, in 32% of cases with unstable angina, and in 13% with acute or subacute infarctions. This is in line with several recent studies indicating safety and procedural success for acute interventions[21,22], especially with back-up of stenting and new antithrombotic regimens[23]. In this study, 61% of interventions for unstable situations were completed with stenting and 5% received abxicimab.

Although single vessel PTCA in one session still represents the majority of procedures, the underlying disease (58% of patients with two and three vessel disease) reflects a trend towards therapy of more complex cases. Differences between countries were identified showing the highest incidence of multivessel disease in patients treated in Germany (64%) and the lowest in the United Kingdom (50%). Since this study was restricted to randomly selected single interventions, planned stepwise dilatation of multivessel disease was not included.

Stenting was performed in 54% of the reported cases and in 49% of target lesions. There was a considerable range in stenting procedures between countries. Most stents were deployed in the United Kingdom, followed by Italy, and the lowest number was found in Belgium. Although the number for the United Kingdom is influenced by one centre stenting all selected patients, the percentage of stenting in the United Kingdom remained the highest after exclusion of this centre. Interestingly the country with the largest number of interventions per million inhabitants, Germany, showed the second lowest stent implantation rate. The disparate use of stenting cannot be explained by the available data. Variables not addressed in this study may determine stenting frequency, among them local reimbursement policies, as well as the personal experience and preference of the operator, which is again biased by the personal case load. The low use of other new therapeutic devices in this study is in accordance with larger series published for Europe[5], but in contrast to single centre reports in Europe[24] and the United States[25]. However, since this study represents a random selection, these numbers probably demonstrate more accurately actual daily practice in Europe.

A satisfactorily low overall complication rate was found, again in accordance with published data[8]. A trend towards relatively higher complication rates in low-volume as compared to high-volume centres could be confirmed[26]. A further interesting finding is the shorter procedure duration of combined angiography/angioplasty procedures (ad hoc cases) compared with stand-alone angioplasties. Two factors may account for this: (1) a preference for ad hoc cases by the more experienced operator and (2) a preference for stand-alone angioplasty for difficult cases. The submission to peer review will further elucidate possible mechanisms engendering complications in individual cases and, therefore, provide a type of quality control superior to comparison of statistical data.

The major limitation of this study is the relatively small number of cases. It was determined on the basis of practicability and not on statistical power analysis. The audit character imposed a limit on the number, as did the planned expert panel rating. However, due to the strict random selection, the statistical data presented in this paper are in keeping with the results of larger databases and, moreover, the accumulated material can also be analysed in a case-oriented approach. Audits are already being performed successfully in Austria[27] as regards cumulated centre data. This study was a first approach in the performance of audits in coronary angioplasty Europe-wide in individual cases. The present logistic restrictions might be overcome in the future by using a combined approach: accumulating procedure data by standardized minimal electronic data sets obligatory for each interventional centre, together with auditing selected cases out of these data sets.

In summary, based on scrutinized hospital and operator data, the study revealed a very high percentage of at least basically justified indications, an adequate procedural success rate, and an acceptably low complication rate. Further analysis by an expert panel will address appropriateness, necessity and procedural performance of individual cases.

The study was supported by the European Society of Cardiology (ESC). The authors gratefully acknowledge the financial support of the following companies: Bard, Cordis (Johnson & Johnson), Devon, Eli Lilly, Guerbet, Guidant, Medtronic, Philips, Schneider, Searle.

References

[1] Grüntzig A. Transluminal dilatation of coronary-artery stenosis [letter]. Lancet 1978; 1: 263.

[2] Grüntzig AR, Senning A, Siegenthaler WE. Nonoperative dilatation of coronary-artery stenosis: percutaneous transluminal coronary angioplasty. N Engl J Med 1979; 301: 61–8.
[3] Röthlisberger C, Meier B. Coronary interventions in Europe 1992. Eur Heart J 1995; 16: 922–929.
[4] Meyer BJ, Meier B, Bonzel T *et al*. Interventional cardiology in Europe 1993. Working Group on Coronary Circulation of the European Society of Cardiology. Eur Heart J 1996; 17: 1318–28.
[5] Windecker S, Meyer BJ, Bonzel T *et al*. Interventional cardiology in Europe 1995. Eur Heart J 1998; 19: 40–54.
[6] Topol EJ, Ellis SG, Cosgrove DM *et al*. Analysis of coronary angioplasty practice in the United States with an insurance-claims data base. Circulation 1993; 87: 1489–97.
[7] National Heart, Lung and Blood Institute Alert 1995 21.
[8] Ryan TJ, Bauman WB, Kennedy JW *et al*. Guidelines for percutaneous transluminal coronary angioplasty. A report of the American Heart Association/American College of Cardiology Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Percutaneous Transluminal Coronary Angioplasty). Circulation 1993; 88: 2987–3007.
[9] L'Obserservateur de L'OCDE: OCDE en chiffres. Statistiques sur les pays membres 1995.
[10] The study group clinical issues, working group Coronary Circulation of the European Society of Cardiology. Recommendations for training and quality control in coronary angioplasty. Eur Heart J 1996; 17: 1477–81.
[11] Monassier JP, Bertrand M, Cherrier F *et al*. [Guidelines for the training of practitioners in coronary angiography and angioplasty, the organization and equipment of centres of coronary angiography and transluminal angioplasty]. Arch Mal Coeur Vaiss 1991; 84: 1783–7.
[12] Cowley MJ, Faxon DP, Holmes DR Jr. Guidelines for training, credentialing, and maintenance of competence for the performance of coronary angioplasty: a report from the Interventional Cardiology Committee and the Training Program Standards Committee of the Society for Cardiac Angiography and Interventions. Cathet Cardiovasc Diagn 1993; 30: 1–4.
[13] Erbel R, Engel HJ, Kübler W *et al*. Richtlinien der interventionellen Koronartherapie. Z Kardiol 1997; 86: 1040–63.
[14] G.I.S. Comitato scientifico et consilio direttivo. Linnee Guida per il laboratori di hemodynamica et di cardiologica interventistica. Hemodynamica 1995; 2: 26–8.
[15] Raj D. *Sampling theory*. New York: McGraw-Hill, 1968.
[16] Gersh BJ, Braunwald E, Rutherford JD. Chronic coronary artery disease. In: Braunwald E, ed. *Heart Disease*. Philadelphia, London, Toronto, Montreal, Sydney, Tokyo: W.B. Saunders 1997: 1331.
[17] Fibrinolytic Therapy Trialists' (FTT) Collaborative Group. Indications for fibrinolytic therapy in suspected acute myocardial infarction: collaborative overview of early mortality and major morbidity results from all randomised trials of more than 1000 patients. Lancet 1994; 343: 311–22.
[18] Campeau L. Letter: Grading of angina pectoris. Circulation 1976; 54: 522–3.
[19] Gleichmann U, Mannebach H, Lichtlen P. [Report on structure and performance statistics of heart catheterization laboratories in Germany. Results of a survey of the Clinical Cardiology Committee of the German Society of Cardiology-Cardiovascular Research 1995]. Z Kardiol 1996; 85: 973–5.
[20] Vogt A, Bonzel T, Harmjanz D *et al*. PTCA registry of German community hospitals. Arbeitsgemeinschaft Leitender Kardiologischer Krankenhausarzte (ALKK) Study Group. Eur Heart J 1997; 18: 1110–4.
[21] Grines CL, Browne KF, Marco J *et al*. A comparison of immediate angioplasty with thrombolytic therapy for acute myocardial infarction. N Engl J Med 1993; 328: 673–9.
[22] Zijlstra F, de Boer MJ, Hoorntje JC, Reiffers S, Reiber JH, Suryapranata H. A comparison of immediate coronary angioplasty with intravenous streptokinase in acute myocardial infarction. N Engl J Med 328; 328: 680–4.
[23] The Epilog Investigators. Platelet glycoprotein IIb/IIIa receptor blockade and low-dose heparin during percutaneous coronary revascularization. N Engl J Med 1997; 336: 1689–96.
[24] Reifart N, Vandormael M, Krajcar M *et al*. Randomized comparison of angioplasty of complex coronary lesions at a single center. Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) Study. Circulation 1997; 96: 91–8.
[25] Mintz GS, Pichard AD, Kovach JA *et al*. Impact of preintervention intravascular ultrasound imaging on transcatheter treatment strategies in coronary artery disease. Am J Cardiol 1994; 73: 423–30.
[26] Ellis SG, Weintraub W, Holmes D, Shaw R, Block PC, King SB. Relation of operator volume and experience to procedural outcome of percutaneous coronary revascularization at hospitals with high interventional volumes. Circulation 1997; 95: 2479–84.
[27] Mühlberger V, Klein W, Mlczoch J, Probst P. [Quality assurance in invasive and interventional cardiology in Austria in 1994. Commissioned by the Interventional Cardiology Working Group of the Austrian Cardiology Society]. Z Kardiol 1996; 85: 647–55.