Original Research

Organization, Structure and Data of the Hellenic Heart Registry on Percutaneous Coronary Interventions: A Step Forward Towards Outcomes Research

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Introduction: The Hellenic Heart Registry on Percutaneous Coronary Interventions (HHR-PCI) was a prospective, observational registry of patients with stable angina or acute coronary syndromes who underwent percutaneous coronary intervention (PCI) between January 2008 and October 2010.
Methods: HHR-PCI was a database that used a secure web-based interface for data entry by individual users. All PCI centers and operators were invited to participate. The participating PCI centers were geographically divided into three main regions: Athens Metro Area, Thessaloniki Metro Area, and Rest of Greece. Indications, demographics, procedural characteristics, and in-hospital outcomes (death, myocardial infarction, cerebrovascular accidents) were recorded.
Results: Eighteen (18) centers participated in the registry (2008-2010) in a systematic fashion, entering complete data for 3441 patients (males 83.1%, mean age 64.1 years, 5521 lesions). PCI was elective in 47.1% of patients and was used to treat an acute coronary syndrome in 52.5%. There were 742 (21.6%) patients treated for ST-segment elevation myocardial infarction, with 225 (30.3%) receiving primary PCI (mean door-to-balloon time 140 minutes). The mean numbers of stents per lesion and per patient were 1.14 and 1.74, respectively, with drug eluting stents being used in 74.2% of coronary lesions. Periprocedural complications were observed in 105 patients (3.1%), while the incidence of in-hospital death, myocardial infarction, and cerebrovascular event were 0.5%, 1%, and 0.6%, respectively.
Conclusions: HHR-PCI was the first web-based national PCI registry in Greece and has provided useful insights regarding the practice of interventional cardiology in this country. Efforts should be made to maintain and extend this type of PCI registry, with a view to improving quality and outcomes research in the field of interventional cardiology.

I n the era of evidenced-based medicine, randomized controlled trials are considered to be the most valuable tool in the clinician's decision-making process. However, in order to study the impact of a specific treatment and to avoid serious adverse effects, high-risk patients with comorbidities are often excluded from randomized controlled trials, and as a result the patient population exam-

ined becomes almost "ideal". It has been proved that patients from randomized controlled trials have fewer risk factors (e.g. younger age, fewer comorbidities) and a better prognosis than the general population seen in everyday clinical practice.[1,2] This gap between evidence from randomized controlled trials and clinical practice may be filled by epidemiological studies and properly designed registries.[3]

Registries, apart from providing a detailed report of the clinical and demographic aspects of a disease, can also reveal the extent to which a disease is treated according to existing guidelines. In small countries like Greece, data can be collected and registered quickly and efficiently, allowing clinicians to compare their own practice with international reference populations, improve the quality and consistency of their practice, and establish cooperation with other clinicians who participate in the registry.[4]

The Hellenic Heart Registry on Percutaneous Coronary Interventions (HHR-PCI) was a registry of patients with stable angina or acute coronary syndromes who underwent percutaneous coronary intervention (PCI). HHR-PCI recorded, at a national level, all hospitals with cardiac catheterization and angioplasty capabilities, operators performing procedures, as well as the basic indications, demographic characteristics, and procedural and outcomes data of patients undergoing PCI.

Methods

Study population

HHR-PCI was a prospective, observational national registry designed to enroll consecutive patients who were admitted with acute coronary syndromes (i.e. unstable angina, myocardial infarction) or stable angina and underwent PCI. Prospective enrollment of patients started in January 2008 in all participating hospitals, and ended in October 2010. HHR-PCI was a database that used a secure web-based interface for data entry by individual users. Each user had a unique identification number and required a password for logging into the database. The Hellenic Society of Cardiology (HSC) was responsible for the central analyses of data at a national level and for the subsequent submission of data to the European Society of Cardiology (ESC) and the European Association of Percutaneous Coronary Interventions (EAPCI).

All PCI centers with active cardiac catheterization laboratories and operators performing PCI in Greece were invited to participate. The participating PCI centers were geographically divided into three main regions: Athens Metro Area, Thessaloniki Metro Area, and Rest of Greece. Out of forty-nine (49) centers, twenty-eight (28) enrolled at least one patient, but eighteen (18) participated in a systematic fashion, recruiting patients on a regular basis. The names of the participating centers and operators are given in the Appendix.

Data collection

Patients' initials and demographic data were recorded for each entry in the database. The electronic case record form also included information regarding patients' past medical history and their major cardiovascular risk factors, as well as data regarding patients' workup, such as their PCI indication, date and time of PCI, admission medications, angiographic findings based on the ESC's 15-segment model,[5] periprocedural medications, additional diagnostic or therapeutic devices used, periprocedural complications, lesion characteristics, and type of stents used. The main outcome measures for this analysis consisted of major in-hospital events (death, myocardial infarction, cerebrovascular accidents).

Data security

A full discussion of database and web security issues has no place in this article, but some of the main features should be mentioned briefly. As mentioned above, all users were assigned a unique username/password combination that was used to log on to the registry. In this way, all transactions were recorded automatically in the web server's log.

Three types of user had different levels of access to the data.

- Ordinary users could enter new procedures and edit data they had entered previously. However, they had no access to (or awareness of) data entered by other users.
- Local administrators could review procedural data entered by all users at their center, but were not allowed to make changes. Local administrators could also edit general information pertaining to their own center.
- National administrators could review data entered by all users in all centers, but were not allowed to make changes. National administrators could also add new centers and monitor general information about all centers.

The web forms were designed to be interactive, limiting or excluding certain options depending on selections made elsewhere so as to avoid the entry of conflicting or spurious data. Wherever possible, data were entered by selection from "drop-down" lists in order to minimize keyboard errors.

All records entered were audited by one of the national administrators (GP, AK) and any apparent discrepancies were referred back to the user who entered the data, so that they could be resolved before the record entry was finalized. Users were not permitted to alter the data while a record was under audit but could do so afterwards if errors were detected. This cycle was repeated as many times as necessary.

The purpose of all the above measures was to ensure the confidentiality of the data while maximizing accuracy.
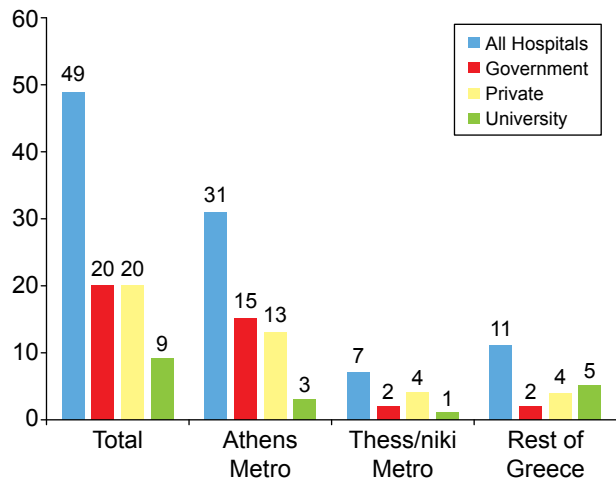
Figure 1. Distribution and type of percutaneous coronary intervention centers among the main geographical regions of the study.

Statistical analysis

Data are expressed as mean ± standard deviation for continuous variables and as percentages for categorical ones. No active comparisons were made between subgroups, as the aim of this study was to present descriptive data concerning PCI at a national level. Statistical analyses were performed using SPSS software (version 18, SPSS, Chicago, IL, USA).

Results

The distribution of the participating PCI centers, the numbers of operators, and the centers having the capability of on-site coronary artery bypass grafting (CABG) in the aforementioned geographical regions of the study, are shown in Figures 1 and 2.

The registry recorded complete data for 3441 patients who were admitted to the 18 fully participating PCI centers between January 2008 and October 2010. The demographic characteristics of these patients are shown in Table 1. The majority of the population were males (83.1%), with a mean age of 64.1 years. Forty-seven percent (47%) of the study participants underwent PCI for stable angina, while non ST-elevation acute coronary syndrome was the indication for PCI in 30.9% and ST-elevation myocardial infarction (STEMI) was the indication in 21.6% (Table 2, Figure 3). There were 742 STEMI patients treated, with 225 (30.3%) receiving primary PCI (within 6 hours of admission) and 517 (69.7%) receiving delayed PCI. The mean door-to-balloon time for patients treated with primary PCI was 140 min, with 57.7% and 65.3% being treated within less than 90 and 120 min, respectively. Angiographic findings and data related to PCI are shown in Tables 3 and 4, respectively. In
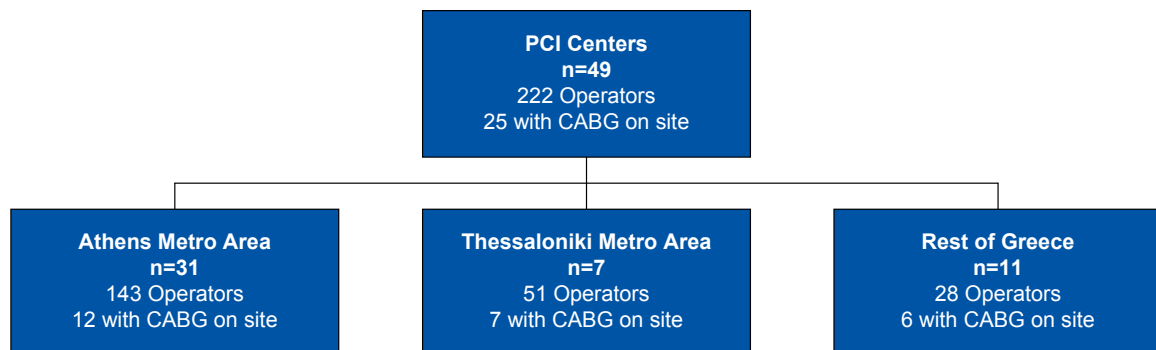
Figure 2. Percutaneous coronary intervention centers, operators, and coronary artery bypass grafting centers among the main geographical regions of the study (2010).

Table 1. Baseline characteristics of patients enrolled in the Registry from January 2008 to October 2010.

|	n (%) or mean ± SD
Total number of patients	3441 (100%)
Males	2859 (83.1%)
Females	582 (16.9%)
Age (years)	64.1 ± 11.1
Height (cm)	169.8 ± 10.8
Weight (kg)	81.9 ± 14.9
BMI	27.9 ± 3.9
Hx Stable angina	877 (25.5%)
Hx Prior MI	797 (23.2%)
Hx CVA	56 (1.6%)
Hx PVD	171 (4,9%)
Hx of CRF	83 (2.4%)
Hx Prior PCI	726 (21.1%)
Hx Prior CABG	225 (9.1%)
Current smokers	1337 (38.9%)
Former smokers	1079 (31.4%)
Current diabetes	1029 (29.9%)
Oral agents - IDDM	601 (17.5%) - 172 (4.9%)
Hypertension	2392 (69.5%)
Dyslipidemia	2311 (67.1%)

SD – standard deviation; BMI – body mass index; Hx – History; CABG – coronary artery bypass grafting; MI – myocardial infarction; CVA – cerebrovascular accident; PVD – peripheral vascular disease; CRF – chronic renal failure; PCI – percutaneous coronary intervention; CABG – coronary artery bypass grafting; IDDM – insulin-dependent diabetes mellitus.

Table 2. PCI Indication (n=3441 patients).

PCI Indication	n (%)
Elective PCI	1622 (47.1%)
ACS (UA-NSTEMI)	441 (12.8%)
STEMI	284 (8.3%)
ACS stabilized	622 (18.1%)
STEMI stabilized	458 (13.3%)
Other	14 (0.4%)

PCI – percutaneous coronary intervention; ACS – acute coronary syndrome; UA – unstable angina; NSTEMI – non ST-segment elevation myocardial infarction; STEMI – ST-segment elevation myocardial infarction.

total, there were 5521 lesions treated (3454 type B, 62.6%) with 82.6% of patients having single- or two-vessel disease. Femoral access was the predominant approach (95.9%) and successful PCI was reported in 97.4% of cases. The mean numbers of stents per lesion and stents per patient were 1.14 and 1.74 respectively, while drug-eluting stents (DES) were used in 4097 (74.2%) of coronary lesions; multi-segment PCI was performed in 63.7% of patients. Clopidogrel (either 300 mg or 600 mg) was administered prior to PCI in 2051 patients (59.6%), while clopidogrel was
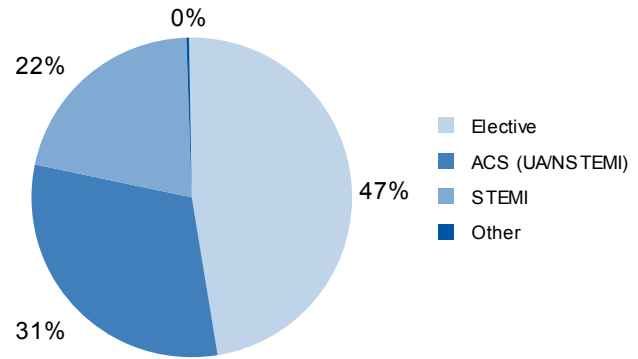
Figure 3. PCI indication (elective: 1622/3441, ACS: 1063/3441, STEMI: 742/3441, Other: 14/3441). PCI – percutaneous coronary intervention; ACS – acute coronary syndrome; UA – unstable angina; NSTEMI – non ST-segment elevation myocardial infarction; STEMI – ST-segment elevation myocardial infarction.

Table 3. Angiographic findings (n=3441 patients).

	n (%)
EF>50%	2460 (71.5%)
30%≤EF≤50%	647 (18.7%)
EF<30%	84 (2.5%)
EF unknown	250 (7.3%)
LM>50%	93 (2.7%)
1VD	1754 (51%)
2VD	1087 (31.6%)
3VD	598 (17.4%)
Cardiogenic shock	18 (0.5%)
Treated LM	67 (1.2%)
Treated LAD*	2189 (39.6%)
Treated CX*	1440 (26.1%)
Treated RCA*	1825 (33.1%)
Treated by-pass graft*	116 (2.1%)

*Lesions (5521 in total). EF – ejection fraction; VD – vessel disease; LM – left main; LAD – left anterior descending artery; CX – circumflex artery; RCA – right coronary artery.

administered during PCI in 1364 patients (39.6%). There was low use of glycoprotein IIb/IIIa inhibitors (11.1%) (Table 5). Periprocedural complications were observed in only 3.1% (n=105) of patients. Periprocedural myocardial infarction (1%), no or slow postprocedural flow (0.9%), side branch occlusion (0.8%), and major bleeding (0.6%) were the most frequent complications. Death, myocardial infarction, and cerebrovascular events occurred in 18 (0.5%), 35 (1%) and 15 (0.4%) patients, respectively (Table 6).

Discussion

The aim of the HHR-PCI was to record the basic indications, demographic, procedural and outcomes

Table 4. Data from 3441 patients (5521 lesions) undergoing percutaneous coronary intervention (PCI).

	n (%)	
Type A lesion	637	(11.5%)
Type B lesion	3454	(62.6%)
Type C lesion	1430	(25.9%)
Restenosis - Bifurcation	197 (3.6%) - 799 (14.5%)	
Direct stenting	876	(15.9%)
PCI with stent	5161	(93.5%)
Mean number of stents per patient	1.74	
Mean number of stents per lesion	1.14	
Mean stent size (mm)	3.08	
Mean stent length (mm)	22.08	
Multi-segment PCI	3517	(63.7%)
Successful PCI	5378	(97.4%)
BMS stenting*	1060	(19.2%)
DES stenting*	4097	(74.2%)
Femoral access	3299	(95.9%)
Radial access	109	(3.2%)
IVUS	74	(2.2%)
Pressure wire	67	(1.9%)
IABP	7	(0.2%)
Distal protection	17	(0.5%)
Thrombectomy	150	(4.3%)
Vascular closure device	1135	(32.9%)

*Stent not specified: 362 (6.6%). BMS – bare-metal stent; DES – drug eluting stent; IVUS – intravascular ultrasound; IABP – intra-aortic balloon pump.

Table 5. Antiplatelet treatment concurrent with percutaneous coronary intervention (PCI) (n=3441 patients).

	n (%)	
Clopidogrel prior to PCI:	2051	(59.6%)
300 mg	1765	(51.3%)
600 mg	286	(8.3%)
<6 hrs	626	(30.5%)
>6 hrs	1425	(59.5%)
Clopidogrel during PCI:	1364	(39.6%)
300 mg	857	(62.8%)
600 mg	507	(37.2%)
GPIIb/IIIa inhibitors (upstream)	99	(2.9%)
GPIIb/IIIa inhibitors (procedural)	383	(11.1%)

GP – glycoprotein.

Table 6. Periprocedural complications and in-hospital outcomes (n=3441 patients).

	n (%)
Periprocedural complications	105 (3.1%)
In-hospital death	18 (0.5%)
Periprocedural MI	35 (1.0%)
Periprocedural CVA	15 (0.4%)
MACE (death/MI/CVA)	65 (1.9%)
No flow/slow flow	31 (0.9%)
Side branch occlusion	28 (0.8%)
Acute segment closure	21 (0.6%)
Major bleed	21 (0.6%)
Repeat PCI	16 (0.5%)
Coronary perforation	13 (0.4%)
Stent thrombosis	15 (0.4%)
Renal failure	11(0.3%)
Distal embolization	12 (0.3%)
Emergency CABG	4 (0.1%)

MI – myocardial infarction; CVA – cerebrovascular accident; MACE – major adverse cardiovascular event; PCI – percutaneous coronary intervention; CABG – coronary artery bypass grafting.

dance with ESC/ACC). Moreover, this registry may be seen as a step forward towards PCI-related quality and outcomes research in our country.

To our best knowledge, this is the first web-based Greek PCI registry. Other efforts to record data, related mainly to major cardiovascular risk factors in Greek patients with acute myocardial infarction, have already been made.[6-8] However, among other data, those regarding interventional procedures in the Greek population come mainly from the HELIOS study.[9] This was a registry of patients with acute myocardial infarction, representing a "decent" sample of all types of hospitals and all geographical regions of our country.

There are several reasons to justify the need for a well organized Greek PCI registry. First of all, registries allow a direct comparison of clinical practice among different hospitals across the country. This can lead to critical improvements in problematic sectors, via the adoption of common therapeutic strategies in all the country's hospitals. In addition, the participation of a wide range of hospitals and investigators in this kind of study improves auditing and enhances clinical responsibility. At the same time, this promotes cooperation among separate national hospitals and medical professionals. Furthermore, the value of national registry data is crucial for national health system administrators, regarding the wise distribution and the optimal utilization of health-related resources. Moreover, it can become the basis for the development of excellent initiatives, such as the Stent

data of consecutive patients undergoing elective or urgent PCI during a three-year period. In addition, a complete record was made of PCI centers, PCI operators and PCI-related details from the entire Greek territory, for both regional and national analyses. This initiative was undertaken by the Working Group of Hemodynamics and Interventional Cardiology of the Hellenic Society of Cardiology with the aim of creating an official national database that would serve educational and professional requirements (in accor-

for Life.[10,11] Last but not least, national registries may serve as the impetus for further clinical research adapted to the special needs of each country.

Regarding the results of our study, it is obvious that there is a large discrepancy, with respect to the number of interventional centers, between the Athens area and the rest of Greece. This is mainly due to the fact that Athens inhabitants represent nearly half the Greek population, and as a consequence the needs of that region are greatly increased. On the other hand, the development of new low-volume (due to geographical position) interventional centers is of debatable value,[12] especially in the setting of STEMI patients.[13]

The demographic characteristics of our patients almost coincide with those of similar previous Greek studies,[6-9] indicating that our study sample is representative of the Greek reality. There was a great predominance of males among patients who underwent PCI, while almost 39% of them were active smokers and 30% were diabetics. In addition, almost 30% of them had a history of previous revascularization (either PCI or CABG), which may raise the need for better public information and more effective application of secondary prevention measures. Regarding the PCI indications, there was a balance between stable angina (47.1%) and acute coronary syndromes (non ST-elevation ACS in 30.9% and STEMI in 21.6% of cases). There is still debate over the value of PCI in patients presenting with stable angina,[14,15] but we have no data with respect to previous imaging studies of this subgroup and that would anyway be beyond the scope of this paper.

Femoral access was used in 96%, while radial access was used in only 4% of cases. This proportion is very low according to international standards[16] and might indicate a need for greater adoption of the radial route, as its advantages in terms of bleeding are unequivocal compared to the femoral route.[17] Indeed, within the past two years, an increasing number of centers have adopted the radial approach as the predominant means of performing diagnostic and interventional procedures. The stent type most used was DES (about 75% of cases), and this was probably due to the more complex type of lesions (only 11.6% were type A) where DES have shown superiority, especially in terms of restenosis-related parameters.[18]

Periprocedural complications were observed in only about 3% of PCI-treated patients. More specifically, we recorded a low incidence of periprocedural myocardial infarction (MI), side-branch occlusion, and major bleeding. In addition, major adverse cerebrovascular events were recorded in about only 2% of the participants. To some extent, these findings probably reflect underreporting of cases with complications (mostly cardiogenic shock), as this was the first effort to report data at a national level. It has to be noted though, that as the registry evolved the number of reported complications increased, possibly as a result of diminishing reluctance on the operators' side. For instance, while periprocedural MI incidence was 0.7% during the first half of the study, it almost doubled during the second half, without there being any significant difference in the type or complexity of the cases performed. Moreover, on an individual basis, many operators did not obtain cardiac enzyme levels post procedure; therefore, the rate of MI reported in this paper does not include some particular patients (silent MIs). It is noteworthy that thrombectomy devices were used in only a low percentage of cases in the acute MI setting. Lastly, successful PCI was reported in the vast majority (97.4%) of cases, which indicates the high quality of the interventional services in Greece.

Our registry has some limitations that need to be taken into consideration. The major one is that, among the 49 centers, only 18 fulfilled the criteria of full participation, recruiting patients on a regular basis. More specifically, of the latter, only 12 (25%) participated in a systematic fashion, since there was no official obligation and participation was left to the operators' discretion. The underlying etiology may have to do with reluctance or low motivation, as well as with a lack of secretarial support in high-volume centers. Last but not least, a loss of operators' enthusiasm as the registry evolved may have played an additional role. However, our registry results almost duplicate other surveys in Europe, and in particular the European PCI registry.[19]

Nevertheless, in an effort to increase our interventional efficacy, in parallel with international standards, the registry can be further developed. Problems of wide participation of hospitals and operators in the registry have to be solved, taking into account the current volunteer basis of the project and in particular the lack of secretarial support. However, given the ease of the web-based entry of cases and the low cost of the whole structure, HHR-PCI should be maintained and adjusted to reality.

Conclusions

HHR-PCI was the first web-based Greek PCI registry, serving as an official national database for educa-

tional and professional requirements. It has provided useful insights regarding the practice of interventional cardiology in the Greek territory, indicating that it is similar to that in other European countries. Efforts should be made to maintain and extend the national PCI registry in order to conform to international standards, thus contributing to the evolution of interventional cardiology in our country.

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Appendix 1. Participating hospitals (alphabetical order).

- Athens Medical Center, Athens
- Euromedica, Thessaloniki
- Gennimatas, Athens
- Hatzikosta, Ioannina
- Hippokration, Athens
- Sismanoglio (1st IKA), Athens
- Interbalkan Center, Thessaloniki
- Iatriko Psyhiko, Athens
- Kyanos Stavros, Athens
- Metropolitan, Athens
- Nikaias, Athens
- Onassio, Athens
- Univ. Hospital, Heraklion
- St. Lukes, Thessaloniki
- Thriassio, Athens
- Univ. Hospital, Alexandroupolis
- Univ. Hospital, Ioannina
- 424 Army, Thessaloniki

Appendix 2. Participating physicians (alphabetical order):

- Achtypis, Dionysis
- Alexopoulos, Dimetrios
- Arampatzis, Chourmouzios
- Avramides, Dimitrios
- Davlouros, Periklis
- Hahalis, Georgios
- Kantzis, Ioannis
- Kapetanopoulos, Athanasios
- Karanikolas, Nikolaos
- Kostopoulos, Konstantinos
- Kotsanis, Athanasios
- Koutsogiannis, Nikolaos
- Maginas, Athanasios
- Mihalis, Lambros

- Olympios, Christoforos
- Papaioannou, Georgios
- Raisakis, Kostis
- Routoulas, Theodoros
- Sassalos, Costantinos
- Sionis, Dimitrios
- Skalidis, Manolis

- Sourgounis, Angelos
- Stefanidis, Ioannis
- Stratigis, Nikolaos
- Triantis, Georgios
- Tsigas, Gregorios
- Tsikaderis, Dimetrios
- Tziakas, Dimitrios