Original Research

Current Management and Quality of Life of Patients with Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention in Greece: 12-Month Results from Antiplatelet Therapy Observational Study II (APTOR II)

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Key words: **Dual antiplatelet treatment, unstable angina, non ST-elevation myocardial infarction, ST-elevation myocardial infarction.**

Introduction: We describe the current management of patients with acute coronary syndromes (ACS) undergoing percutaneous coronary intervention (PCI) over 12 months in Greece.

Methods: This was a prospective observational study in ACS patients undergoing PCI from September 2008 to April 2009, capturing practices over 12 months at 22 sites that enrolled 558 eligible patients.

Results: A total of 351 patients suffered from unstable angina or non-ST elevation myocardial infarction (UA/NSTEMI), while 207 patients suffered from ST-elevation myocardial infarction (STEMI). For the UA/NSTEMI group, the median age was 64 years (interquartile range: 55-73), while for the STEMI group the median age was 56 years (interquartile range: 49-66). Stents were placed in 96.4% of patients: bare-metal stents alone were placed in 19% of patients, drug-eluting stents alone in 77.5% of patients, and both types of stent in 3.5% of patients. 74% of UA/NSTEMI patients and 87% of STEMI patients received the first antiplatelet loading dose within 1 day of the episode. 76% of UA/NSTEMI patients underwent PCI within 3 days following the initial ACS symptoms, while 67% of STEMI patients underwent PCI within 1 day of the ACS symptoms. Follow-up data were available for 540 (96.8%) patients. The percentages of patients on antiplatelet therapy and on other medications at the time of hospital discharge and at 12 months post-PCI were as follows: aspirin 98%, 97%; clopidogrel 99%, 96%; statins 81%, 79%; beta-blockers 73%, 72%; calcium blockers 11%, 11%; angiotensin II receptor blockers/angiotensin-converting enzyme inhibitors 64%, 62%; proton-pump inhibitors 39%, 35%.

Conclusions: In ACS patients treated with PCI in Greece, dual antiplatelet treatment is maintained in a very high percentage through 1 year post-procedure, and drug-eluting stent use is also high.

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Patients experiencing acute coronary syndromes (ACS) require immediate hospital admission. Over the last 2 decades, new and effective treatment strategies have been developed that have both reduced short-term mortality and increased long-term survival rates in patients with ACS.[1-5] Current practice includes rapid patient evaluation and risk stratification based on clinical and electrocardiographic characteristics, as well as the assessment of biochemical markers.[6-13] The majority of ACS patients who are at high risk for subsequent car-

diovascular complications receive immediate intravenous or subcutaneous anticoagulation treatment. In addition, they receive dual antiplatelet treatment.[14] These patients also immediately undergo cardiac catheterisation and percutaneous coronary intervention (PCI). At hospital discharge, physicians recommend that long-term dual antiplatelet therapy should last for a year at the minimum. Treatment with statins, and possibly with angiotensin-converting enzyme inhibitors and b-blockers, is also recommended. However, despite these measures, 10% of ACS patients suffer either re-infarction or stroke, or die within one year from hospital discharge.[1-5] It has been shown that the risk of mortality and morbidity varies among patient populations.[15,16] This variability has generated intense research and has led to the development of new antithrombotic agents and novel practices.[15-21]

Currently, there is little understanding in the European setting of the factors that determine ACS patients' utilisation of healthcare resources and costs for the 12-month period that follows hospital admission for PCI. There are also a number of unknown factors characteristic of a clinical population: the actual pattern of antiplatelet therapy doses, the length of treatment in clinical practice over a complete 12-month period, the relationship between what the hospital consultant expects and what the primary care physician prescribes, the actual clinical event rate over 12 months, the overall costs over 12 months, including hospital and primary care, and the impact of subsequent cardiovascular events on quality of life.

Documenting patient outcomes, use of medical resources, and patient quality of life, is of paramount importance. The APTOR II study (a 12-month prospective, observational study) attempted to accurately describe the characteristics of the European clinical population. The primary objective was to assess the 12-month direct healthcare resource use and the estimated costs following PCI with associated antiplatelet therapy for ACS patients. Secondary objectives were to describe the health-related quality of life and clinical outcomes following PCI with associated antiplatelet therapy for ACS patients (including drug doses, duration of therapy, and readmission rates), and to explore the relationship of antiplatelet dose and duration of therapy with resource use, estimated costs, health-related quality of life and clinical outcomes. This report describes the data with regard to the current management over 12 months of ACS patients in Greece undergoing PCI.

Methods

The APTOR II study was a non-interventional, prospective, observational cohort study. Eleven countries participated: Czech Republic, Germany, Greece, Norway, Sweden, Finland, Denmark, Austria, Hungary, Belgium, and the Netherlands. Five hundred patients were required from each country or from each cluster of countries. Three clusters were formed: Norway, Sweden, Finland and Denmark (cluster 1), Belgium and the Netherlands (cluster 2), Austria and Hungary (cluster 3). Participating patients were suffering from ACS and underwent PCI. In Greece, patients were enrolled from September 2008 until April 2009. Similar data from countries that participated in APTOR I (Spain, United Kingdom, and France) were added for the collective registry APTOR I and II.

Patient inclusion criteria

At least 18 years of age, diagnosis of ACS, normal course of care for PCI intervention, and either initiation or continuation of antiplatelet therapy; at study entry, patients were not simultaneously participating in a study that included an investigational drug or procedure. All patients were fully informed, gave their written consent for the use of their data and had sufficient understanding of the Greek language to enable them to complete the questionnaires.

Patient data were held by each healthcare provider. Data were collected at specific time points: during study admission, at hospital discharge, at 6 months following hospital discharge, and at 12 months following PCI.

- Study admission data: initial medical history and any preexisting conditions, national and international risk scores, demographics, antiplatelet and concomitant medication and clinical events.
- In-hospital data before discharge: resource use, antiplatelet and concomitant medication, clinical events and quality of life assessment.
- Six-month data: resource use, antiplatelet and concomitant medication and cardiovascular disease.
- One-year data: resource use, antiplatelet and concomitant medication, cardiovascular disease and quality of life assessment.

For all patients, resource use, antiplatelet medications, concomitant medications, and cardiovascular complications were recorded. Cardiovascular complications included unstable angina (UA), non ST-elevation myocardial infarction (NSTEMI), ST-elevation

myocardial infarction (STEMI), urgent target vessel revascularisation, acute heart failure, ischaemic and haemorrhagic strokes, and fatal cardiovascular disease. Healthcare resource use included cardiovascular-related procedures, hospital stays, and visits to healthcare professionals. Quality of life was measured using the EuroQoL EQ-5DTM health index (a standardised five-item instrument for use as a measure of health outcome) and the visual analogue scale at hospital discharge and at 1 year post-PCI.

Statistical analysis

Twelve-month Kaplan–Meier estimates and 95% confidence intervals (CI) were calculated for clinical events in the 12 months following PCI. All patients eligible at baseline were included in the analysis of in-hospital events. For the analysis of activity following hospital discharge, all eligible patients with 12-month follow-up data were included. Baseline patient data were reported using descriptive statistics and 95% CI where appropriate. For continuous variables, mean, standard deviation, median, minimum, maximum, and quartiles were calculated. Absolute numbers and percentages (including missing values) were given for categorical variables. Overall analyses and per-country analyses were performed.

Results

A total of 3088 patients were included from 11 European countries. In Greece, 559 patients were enrolled from September 2008 until April 2009, from 22 active investigator sites. Of these, 558 patients were eligible for the study and 540 patients (96.8%) successfully completed study participation 1 year after study entry.

Three hundred and fifty-one patients (62.9%) were admitted with the diagnosis of UA/NSTEMI, and 207 patients (37.1%) were diagnosed with STEMI. Eighty-five percent of patients who suffered from UA/NSTEMI and 90% of those who suffered from STEMI were admitted to the hospital within 1 day of symptom onset.

Approximately similar percentages of patients received a loading dose of aspirin and clopidogrel upon hospital admission. Only 13% of UA/NSTEMI patients received a 600 mg loading dose of clopidogrel, while 30% of STEMI patients received a 600 mg loading dose. Almost all patients received a maintenance dose of 75 mg clopidogrel at hospital discharge while only 2% of STEMI patients received 150 mg of clopidogrel. Ninety percent of UA/NSTEMI patients were discharged on a 100 mg dose of aspirin, while only 76% of STEMI patients were prescribed a 100 mg dose of aspirin and 22% received a dose of 325 mg.

The patients' ages and baseline characteristics are shown in Table 1.

Seventy-six percent of UA/NSTEMI patients underwent PCI within the first 3 days following initial ACS symptoms, while 67% of STEMI patients underwent PCI within 1 day of the ACS symptoms. Stents were placed in 96.4% of patients: bare-metal stents alone were placed in 19% of patients, drug-eluting stents alone in 77.5%, and both types of stent in 3.5% of patients. The types of stents and procedural characteristics are shown in Table 2.

Upon hospital discharge, almost all patients re-

Table 1. Baseline characteristics.

	UA/NSTEMI n=351	STEMI n=207	Total n=558
Age (median, IQR)	64 (55, 73)	56 (49, 66)	62 (52, 71)
≥75 years	74 (21.1%)	23 (11.1%)	97 (17.4%)
Gender (male)	284 (80.9%)	176 (85.0%)	460 (82.4%)
Weight, median (IQR)	80 (72, 90)	82 (72, 90)	81.5 (72, 90)
<60 kg	11 (3.1%)	13 (6.3%)	24 (4.3%)
Body mass index, median (IQR)	27.8 (25.6, 30.1)	27.4 (24.9, 29.4)	27.7 (25.3, 30.0)
Body mass index ≥30	99 (28.2%)	44 (21.3%)	143 (25.6%)
Hyperlipidaemia	236 (67.2%)	115 (55.6%)	351 (62.9%)
Hypertension	234 (66.7%)	115 (55.6%)	349 (62.5%)
Diabetes type I	1 (0.3%)	1 (0.5%)	2 (0.4%)
Diabetes type II	90 (25.6%)	35 (16.9%)	125 (22.4%)
Previous PCI	73 (20.8%)	12 (5.8%)	85 (15.2%)

UA – unstable angina; NSTEMI – Non ST-elevation myocardial infarction; STEMI – ST-elevation myocardial infarction; IQR – interquartile range; PCI – percutaneous coronary intervention.

Table 2. Index procedure.

	UA/NSTEMI n=351		STEMI n=207		Total n=558	
PCI procedure:						
With stent	341	(97.2%)	197	(95.2%)	538	(96.4%)
Without stent	10	(2.8%)	10	(4.8%)	20	(3.6%)
Type of stent:						
BMS only	33	(9.7%)	69	(35.0%)	102	(19.0%)
DES only	298	(87.4%)	119	(60.4%)	417	(77.5%)
BMS & DES stents	10	(2.9%)	9	(4.6%)	19	(3.5%)
>1 Stent	149	(42.5%)	70	(33.8%)	219	(39.2%)
Access site:						
Femoral	343	(97.7%)	202	(97.6%)	545	(97.7%)
Radial	8	(2.3%)	5	(2.4%)	13	(2.3%)
Fibrinolytic therapy prior to PCI:						
No	347	(98.9%)	149	(72.3%)	496	(89.0%)
Yes	4	(1.1%)	57	(27.7%)	61	(11.0%)
Glycoprotein IIb/IIIa Inhibitors	59	(16.8%)	75	(36.2%)	134	(24.0%)

UA – unstable angina; NSTEMI – non ST-elevation myocardial infarction; STEMI – ST-elevation myocardial infarction; PCI – percutaneous coronary intervention; BMS – bare metal stent; DES – drug-eluting stent.

Table 3. Medication use (% of patients) from hospital discharge to 12 months post-PCI.

	UA/NSTEMI			STEMI		
Medication	Discharge	6 months	1 year	Discharge	6 months	1 year
Aspirin	96.8	97.7	97.4	100	99.5	97.5
Clopidogrel	98.5	99.1	96.5	100	99.5	93.9
Statin	80.4	79.5	78.4	82.8	79.8	78.8
b-blocker	69.9	70.2	69.6	78.3	76.3	76.3
ACE Inh/ARB	64.3	62.3	62.3	64.6	62.6	61.1
Ca^{++} blocker	13.5	14	12.3	5.6	8.6	7.6
Cholesterol absorption inhibitor	1.5	1.5	1.5	2.0	2.0	2.0
Anti-anginal	28.1	25.1	23.7	23.7	19.7	16.7
Diuretic	9.1	9.9	9.9	10.6	12.6	11.1
PPI	35.4	35.7	31.6	46.5	43.4	39.9

UA – unstable angina; NSTEMI – non ST-elevation myocardial infarction; STEMI – ST-elevation myocardial infarction; ACE Inh – angiotensin-converting enzyme inhibitor; ARB – angiotensin receptor blocker; PPI – proton pump inhibitor.

ceived dual antiplatelet treatment and continued treatment throughout the year following PCI. The percentages of patients on dual antiplatelet treatment and other medications on discharge, at 6 months and 1 year are shown in Table 3.

Regarding dietary habits, 7.3% of patients with UA/NSTEMI and 5.6% with STEMI were enrolled in a formal diet regimen. One year post-PCI, the same number of patients continued with the same regimen. Upon leaving the hospital, 7.9% of UA/NSTEMI patients and 3% of STEMI patients followed their doctor's directions regarding physical exercise. At the end of 1 year post-PCI, the percentage of exercise followers remained unchanged for the UA/NSTEMI group and increased to 3.5% for the STEMI group.

Most of the patients in Greece remained on dual antiplatelet therapy throughout the 12-month follow-up period and only few patients discontinued aspirin or clopidogrel therapy within a year from PCI.

The clinical events that occurred within the year following discharge are shown in Table 4. A few patients experienced at least one cardiovascular event within 1 year after PCI (overall 9% for both groups). Bleeding events, despite the dual antiplatelet treatment for the whole year, were rarely observed.

Few cardiovascular events and/or haemorrhages requiring readmission (planned or unplanned) were observed (Table 5).

Table 4. Clinical events.

	UA/NSTEMI (n=351)	STEMI (n=207)	Total (n=558)
Number of patients still at CV risk at 1 year	300	178	478
UA	[16] 4.6% (2.4, 6.8)	[10] 4.8% (1.9, 7.8)	[26] 4.7% (2.9, 6.5)
NSTEMI	[2] 0.6% (0,1.4)	0	[2] 0.4% (0, 0.9)
STEMI	[2] 0.6% (0, 1.4)	[2] 1.0% (0, 2.4)	[4] 0.7% (0, 1.4)
Haemorrhagic stroke	0	0	0
Ischaemic stroke	[1] 0.3% (0, 0.8)	[1] 0.5% (0, 1.4)	[2] 0.4% (0, 0.9)
Urgent target vessel revascularisation	0	0	0
Acute heart failure	[3] 0.9% (0, 1.8)	[4] 1.9% (0.1, 3.8)	[7] 1.3% (0.3, 2.2)
Stent thrombosis	[2] 0.6% (0, 1.4)	[1] 0.5% (0,1.4)	[3] 0.5% (0, 1.2)
Death	[3] 0.9% (0, 1.8)	[3] 1.5% (0, 3.2)	[6] 1.1% (0.2, 2.0)
Death (CV-related)	0	[2] 1.0% (0, 2.4)	[2] 0.4% (0, 0.9)
Composite outcome*	[5] 1.4% (0.2, 2.7)	[4] 2.0% (0.1, 3.9)	[9] 1.6% (0.6, 2.7)

[n]=number of patients who experienced the event; %=Kaplan–Meier estimate (confidence interval).
*Any one of the following: NSTEMI, STEMI, haemorrhagic stroke, ischaemic stroke, CV-related death.
UA – unstable angina; NSTEMI – non ST-elevation myocardial infarction; STEMI – ST-elevation myocardial infarction; CV – cardiovascular.

Table 5. Hospital readmission for a CV or bleeding event.

	UA/NSTEMI (n=344)	STEMI (n=198)	Total (n=542)
Planned re-hospitalisation:	2 (0.6)	7 (3.6)	9 (1.7)
PCI performed	1 (50.0)	4 (57.1)	5 (55.6)
CABG performed	0	1	(14.3) 1 (11.1)
Implantation of cardiac pacemaker	0	0	0
Hospital readmission:	19 (5.6)	12 (6.1)	31 (5.8)
PCI performed	9 (47.4)	3 (25.0)	12 (38.7)
CABG performed	0	0	0
Implantation of cardiac pacemaker	0	0	0

Data are given as number (%). UA – unstable angina; NSTEMI – non ST-elevation myocardial infarction; STEMI – ST-elevation myocardial infarction; CV – cardiovascular; PCI – percutaneous coronary intervention; CABG – coronary artery bypass graft.

The resource use for healthcare services is shown for UA/NSTEMI patients in Figure 1 and for STEMI patients in Figure 2. The quality of life assessment by the end of the year is shown in Table 6.

Discussion

The study was carried out successfully. The results accurately describe the current management pathways in patients with ACS who underwent PCI in Greek hospitals, their hospital stay and their subsequent 1-year course. This study also examined the effect of these practices on the overall resource use and on the quality of life of patients for the year that followed PCI. Comparisons with the existing European Society of Cardiology guidelines can also be made.[3,4]

The majority of patients with ACS who underwent PCI were admitted to the hospital on the first day of the onset of symptoms (79% of UA/NSTEMI patients and 86% of STEMI patients). The timing of the loading dose of clopidogrel (given in 74% of UA/NSTEMI patients and 87% of STEMI patients) was almost identical: 87% of UA/NSTEMI patients and 91% of STEMI patients received the clopidogrel loading dose on the same day they were admitted to hospital. The Greek data also show that almost all patients were admitted directly to the hospital of treatment, with very few ambulance transfers. [22]

Three quarters (76%) of the UA/NSTEMI patients and two thirds (67%) of the STEMI patients underwent PCI within the first 72 hours of experiencing ACS symptoms. For the UA/NSTEMI patients, this is in accordance with the time of intervention in the interventional arm of most trials, comparing invasive versus non-invasive treatment in such patients.[23-27] Current European Society of Cardiology

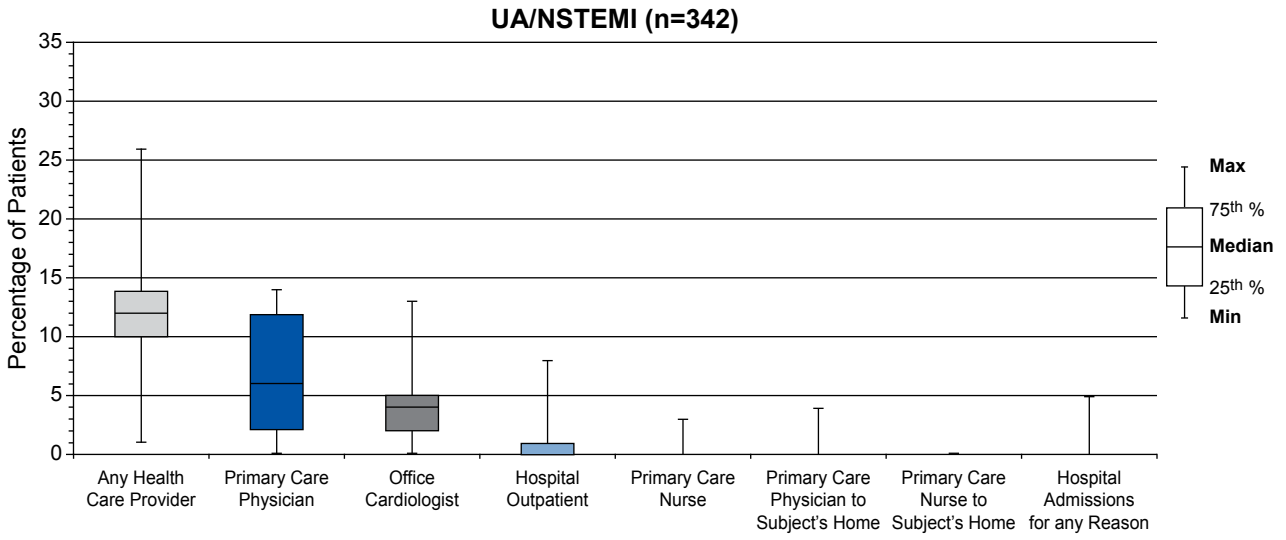

Figure 1. Resource use for healthcare services throughout 1 year for patients with unstable angina (UA) or non ST-elevation myocardial infarction (NSTEMI).

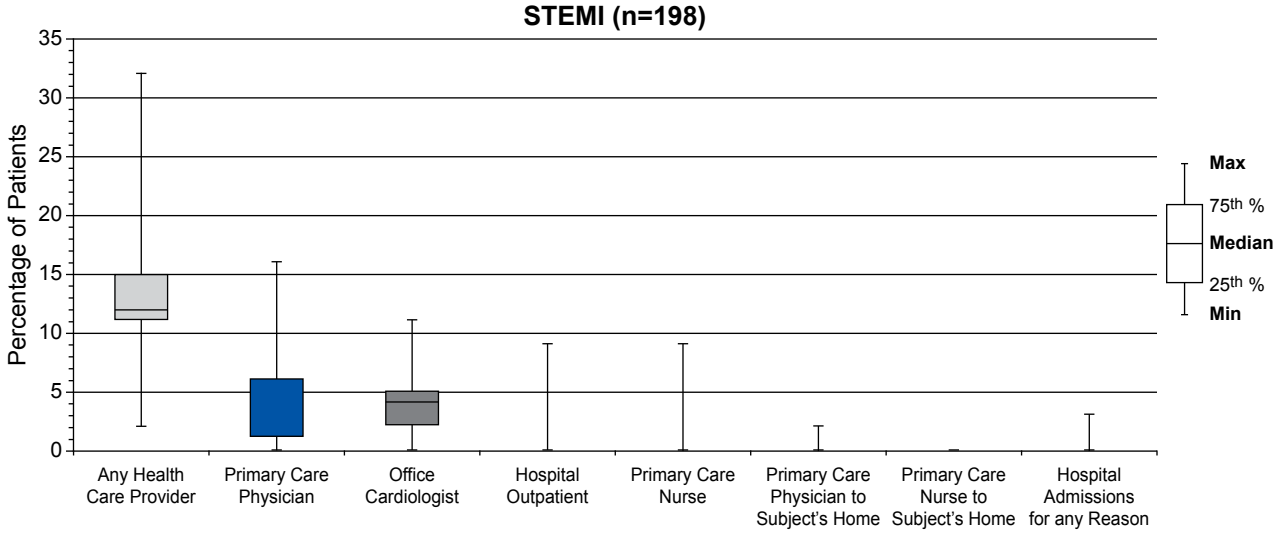

Figure 2. Resource use for healthcare services throughout 1 year for patients with ST-elevation myocardial infarction (STEMI).

Table 6. Change in quality of life.

	Health state index (HSI)			Visual analogue scale (VAS)†		
Index diagnosis	n	Median (IQR)	Mean (SD)	n	Median (IQR)	Mean (SD)
UA/NSTEMI (n=342)	338	0.00 (0, 0.15)	0.02 (0.21)	341	5 (0, 10)	5.86 (14.27)
STEMI (n=198)	195	0.00 (0, 0.12)	0.03 (0.21)	196	5 (0, 15)	8.80 (13.26)
Overall (n=540)	533	0.00 (0, 0.12)	0.02 (0.21)	537	5 (0, 15)	6.93 (13.97)

†Higher VAS score represents better health.
UA – unstable angina; NSTEMI – non ST-elevation myocardial infarction; STEMI – ST- elevation myocardial infarction; IQR – interquartile range; SD – standard deviation; n – number of subjects.

and American College of Cardiology guidelines for treatment follow this timeframe, although there are emerging data to suggest that interventions should be performed earlier, 24-48 h from the start of the episode.[28,29] For the STEMI patients, our data probably reflect a mixed population, including both those patients who underwent primary PCI and those who were not treated with primary PCI but underwent catheterisation and PCI prior to hospital discharge.

Regarding procedural techniques, in Greece, radial artery access was used in only 2% of patients with UA/NSTEMI, while this percentage is 45% in the Nordic countries.[30]

One of the most important findings was that 90% of patients suffering from UA/NSTEMI and 60% of patients suffering from STEMI were treated with drug-eluting stents. This was the highest among all participating countries. In all other countries, drug-eluting stents were placed in less than 50% of patients, with the lowest recorded in the Czech Republic (22% for UA/NSTEMI and 8% for STEMI).[31] There is no obvious reason for this difference. During the period of data collection, a number of studies and meta-analyses established the safety of drug-eluting stent use in STEMI patients.[32] Cost issues could possibly have influenced the choice between the two types of stent, although there are no supporting data.

The high frequency of drug-eluting stent placements in Greece could partly explain the large number of patients treated with dual antiplatelet agents (97.4% for UA/NSTEMI and 97.5% for STEMI) during the year that followed PCI. This practice is in accordance with the European Society of Cardiology and American College of Cardiology guidelines, where dual antiplatelet therapy is recommend for 1 year following PCI, regardless of the stent type used.[1,3] This was not the practice in all participating countries. In the Czech Republic for instance, fewer than 50% of patients were receiving dual antiplatelet therapy 6 months post PCI.[33] It is also worth noting that in Greece, 1 year after PCI, a very high percentage of patients were on statins, b-blockers and angiotensin-converting enzyme inhibitors, while 31.6% and 39.9% of UA/NSTEMI and STEMI patients, respectively, were on a proton-pump inhibitor for gastrointestinal protection (Table 3). In addition, the clinical event rate was very low for this group of patients at 1 year of follow up (overall 4.8% for a new episode of UA, 0.4% for NSTEMI, 0.7% for STEMI, 0.4% for an ischaemic stroke, 1.1% for death). Few overall stent thromboses (0.6%) and overall serious bleeding events (0.7%) were recorded during the same time period of 1 year after PCI.

There is no clear explanation why so few clinical and haemorrhagic events were observed in this registry. The same finding was observed for all patients from the other participating countries. The recorded rates of major adverse cardiac events and serious bleeding events were lower compared to the clopidogrel arm of current randomised trials of ACS patients treated with PCI, such as the TRITON-TIMI 38[21] and PLATO[20] studies. In these two trials, the primary endpoint of cardiovascular death, myocardial infarction or stroke within 1 year was greater than 10% for the clopidogrel arm (12.1% for TRITON-TIMI 38[21] and 11.7% for PLATO[20]), while TIMI major bleeding not related to coronary artery bypass grafting was recorded in 1.8% of patients by TRITON-TIMI 38[21] and 2.2% by PLATO.[20] One possible explanation is patient selection. Greek patients suffering from ACS were selected after hospital admission, many of them on the basis of a successful PCI. However, not all patients satisfying the selection criteria were enrolled. This potential case selection should be taken into account when interpreting the data, and it can probably serve as an explanation for the low rate of major adverse cardiac events recorded. Moreover, events prior to PCI were not reported. Therefore, the participating population was at low risk for subsequent cardiovascular complications. However, this finding would possibly not be reproduced if a large trial with a consecutive number of randomised patients was carried out. Another potential explanation for the low ischaemic event rate could be the different methodology in the endpoint of assessment: biomarkers for myocardial infarction detection in randomised clinical trials versus solely site-reported events in observational studies.

Healthcare resource use was recorded for the total number of patients and was mainly provided by primary care physicians (79.7%) and office cardiologists (92.9%). A disappointing finding was the very low rate of patient enrolment in a formal diet and/or exercise program. By the end of the year following PCI, only 5.6% and 3.5% of STEMI patients, and 7.3% and 7.9% of NSTEMI/UA patients, were on a formal diet and exercise program, respectively. The lack of reimbursement for such programs by the Greek insurance carriers could possibly influence the current trend, since diet and exercise programs are not part of recommended care in Greece and the majority of patients are not offered these programs.

Patients discharged from the hospital scored high

in quality of life (median EQ-5D health state index at 0.85, interquartile range: 0.76-1.00).

Limitations

The study has the limitations of an observational non-interference trial. Although a large number of ACS patients undergoing successful PCI were recorded during a fairly short period, reflecting current practice, probably not all patients with ACS admitted to those hospitals were included. However, the purpose of the trial was to record current practices regarding PCI and the medications used, in relation to resource use and patients' quality of life.

Conclusions

APTOR II was a prospective observational study that aimed to capture current health management in Greece and enrolled 559 patients who suffered from ACS. The results show that, for the majority of patients, PCI was performed via the femoral route and according to the existing guidelines. In addition, most patients underwent PCI within 72 hours following ACS. Drug-eluting stents were placed in a high proportion of patients, and dual antiplatelet treatment was maintained in a very high percentage throughout the year that followed the PCI procedure.

These real-life data reflect treatment patterns among ACS patients managed by PCI in Greece during 2008-2009. They provide a useful benchmark for comparison with European guidelines, and should help strengthen efforts to achieve international best practice.

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