Trends in cardiovascular risk factors and their treatment among patients discharged from Divisions of Internal Medicine. The FAPOI-1 and FADOI-2 studies

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Background. **There is an increasing interest in monitoring cardiovascular risk factor levels and their treatment. Two studies were run in patients discharged from Divisions of Internal Medicine.**

Methods. **Two studies, respectively conducted in 1996 and 1999, have collected data on the diagnoses of cardiovascular diseases and cardiovascular risk factor levels and treatment in 6450 and 8133 patients (age ≥ 35 years) discharged during 1 week from 235 and 345 Italian Divisions of Internal Medicine.**

Results. **The second survey revealed: a relative increase in heart failure and cerebrovascular disease diagnoses; lower serum levels of total cholesterol and triglycerides, lower systolic and diastolic blood pressure mean levels, and a decreased incidence of the habit of smoking among males. The proportion of treated hypertensives (blood pressure ≥ 140/90 mmHg, or the use of antihypertensive drugs) increased slightly (65 to 68% among men and 69 to 71% among women). A reduction in the use of ACE-inhibitors was observed, balanced by an increase in the use of angiotensin II antagonists. The proportion of treated dyslipidemic patients (total cholesterol levels ≥ 250 mg/dl, or HDL cholesterol levels < 35 mg/dl or triglyceride levels ≥ 200 mg/dl or the use of hypolipidemic drugs) significantly increased from 10 to 25% among males and from 12 to 25% among females, due to a substantial increase in the use of statins.**

Conclusions. **During a 3-year period increasing attention for cardiovascular risk factors and their treatment among patients discharged from Divisions of Internal Medicine has been documented. In particular, there has been a large increase in the use of statins, although large segments of patients may need further attention and drug treatment.**

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Introduction

Two projects recently concluded 3 years apart had the purpose of describing, in large populations of patients discharged from Divisions of Internal Medicine in Italy, the relative prevalence of the most common diagnoses, the mean levels of some cardiovascular risk factors, and the prescribed treatment for the same risk factors. Major findings have been independently reported elsewhere for the two studies[1,2].

There were some slight methodological differences in the two studies but some basic comparisons are anyhow feasible at least for one subgroup of variables.

The purpose of this analysis was to review the two studies in a comparative way, and to describe the time trends in the relative prevalence of major cardiovascular diagnoses and in cardiovascular risk factor mean levels and their treatment, during a 3-year period.

This may help in monitoring the attention and attitude of physicians towards cardiovascular risk factors, their treatment and cardiovascular prevention in general which seems to be a very sensitive issue in the present era of treatment and prevention, even outside the area of specialists in cardiology.

Methods

In both projects, named FAPOI-1 and FADOI-2, data were collected from the clinical records of patients discharged dur-

ing the last week of October 1996 and 1999 respectively. The two projects recruited 235 and 345 Divisions of Internal Medicine spread all over the country respectively. Overall, 6450 patients were considered in the first study and 8133 in the second study.

Since the focus was made on the problems related to cardiovascular diseases and their risk factors, the comparative analysis was limited to subjects aged ≥ 35 years for a total of 5904 and 7576 patients respectively.

Data were collected in a standard way from the original clinical records, dealing with general information, the values of measured cardiovascular risk factors, the awareness on the presence of certain conditions such as hypertension and dyslipidemia, the official discharge diagnoses, the reconstructed cardiovascular diagnoses based on defined criteria, and the treatment of some cardiovascular risk factors as prescribed at discharge.

Further details on the methodology may be found in the original papers[1,2].

Results

In table I the age and sex distribution of the patients aged ≥ 35 years and enrolled in the two studies are given. Testing the distributions by the χ^2 test suggested that there was no statistically significant difference between the two study populations and therefore the original data were treated without computing any age standardization.

In table II the relative frequencies of some cardiovascular diagnoses are reported, separately for men and women. Unfortunately the diagnoses of coronary heart

disease, cerebrovascular disease and peripheral artery disease and the pool of these conditions as derived from the review of clinical records, were based on slightly different criteria and therefore the comparison is subject to uncertainties.

On the other hand, the discharge diagnoses (based on the 9th revision of the WHO-ICD criteria)[3] were methodologically comparable. They suggest a reduction in the relative proportion of acute myocardial infarction which was not statistically significant for males, but significant for females. The overall diagnosis of coronary heart disease is less common in both genders but this is statistically significant only for men.

On the other hand, the increase in the incidence of heart failure and cerebrovascular disease was statistically significant in both genders, while the changes in the relative frequency of peripheral artery disease were not so.

Finally, the relative proportion of hypertensives (defined by *ad hoc* criteria) was slightly lower (significantly only for women) whereas the relative proportion of the *ad hoc* definition of dyslipidemia and of diabetes did not show any substantial differences between the two studies.

Table III gives the mean levels, separately for men and women, of some cardiovascular risk factors collected in the two studies. Slight but statistically significant reductions are seen between the first and the second study for the systolic and diastolic blood pressures, total cholesterol and non-HDL cholesterol in both genders. The serum triglyceride levels were statistically lower in the second study among women, while no changes were seen for HDL cholesterol. The blood glucose increased in a non-significant fashion among men whereas it decreased significantly among women. The mean levels of serum creatinine seemed to be stable among men and slightly but significantly lower among women. The relative proportion of smokers was stable among women, while it was slightly but significantly lower among men.

The use of a small series of drugs, comparable between the two studies and dealing with all the patients considered in this analysis, is given in figure 1. Between 1996 and 1999 there has been a significant decrease in the use of ACE-inhibitors largely balanced by the increase in the use of angiotensin II antagonists. An increase has been recorded in the use of beta-blockers and alpha-blockers, whereas calcium antagonists have been used with a similar frequency in the two studies. Overall, the use of antihypertensive drugs did not change significantly between the two studies. No changes were recorded in the use of fibrates while there was a marked increase in the use of statins and, consequently, in the use of hypolipidemic drugs. In particular, the overall use of statins moved from 2 to 6% in all patients. Altogether, all changes were statistically significant except for calcium antagonists, the overall antihypertensive drugs, fibrates and other hypolipidemic drugs, in both genders.

Table I. Distribution by sex and age of patients aged ≥ 35 years in the two studies.

	FAPOI-1 (1996)	FADOI-2 (1999)
Men		
Age (years)		
35-44	174 (6%)	230 (6%)
45-54	333 (11%)	413 (12%)
55-64	585 (20%)	681 (19%)
65-74	896 (31%)	1110 (31%)
75-84	683 (23%)	799 (22%)
≥ 85	248 (9%)	372 (10%)
Total	2919 (100%)	3605 (100%)
Women		
Age (years)		
35-44	147 (5%)	181 (5%)
45-54	261 (9%)	307 (8%)
55-64	492 (16%)	614 (16%)
65-74	797 (27%)	976 (25%)
75-84	824 (28%)	1137 (29%)
≥ 85	464 (15%)	656 (17%)
Total	2985 (100%)	3871 (100%)

The age distribution of both genders does not statistically differ between the two studies.

Table II. Prevalence of some diseases and conditions in the two studies. Men and women aged ≥ 35 years.

	FAPOI-1 (1996)	FADOI-2 (1999)	p
Men			
Clinical criteria*			
Coronary heart disease	2826 (44.4%)	3393 (40.8%)	–
Cerebrovascular disease	2824 (24.5%)	3427 (28.5%)	–
Peripheral artery disease	2765 (17.5%)	3392 (23.1%)	–
Cardiovascular atherosclerotic disease	2694 (54.3%)	3676 (47.3%)	–
Discharge diagnosis			
Acute myocardial infarction	2942 (1.8%)	3676 (1.5%)	0.390
Coronary heart disease	2942 (13.7%)	3676 (11.9%)	0.032
Heart failure	2942 (3.8%)	3676 (8.5%)	< 0.001
Cerebrovascular disease	2942 (13.5%)	3676 (16.5%)	< 0.001
Peripheral artery disease	2942 (5.6%)	3676 (5.0%)	0.303
Ad hoc criteria			
Arterial hypertension§	2852 (74.3%)	3574 (72.2%)	0.063
Dyslipidemia§§	2942 (25.0%)	3676 (25.7%)	0.534
Diabetes§§§	2811 (22.9%)	3574 (24.1%)	0.275
Women			
Clinical criteria*			
Coronary heart disease	2906 (43.5%)	3676 (39.2%)	–
Cerebrovascular disease	2894 (27.9%)	3722 (30.6%)	–
Peripheral artery disease	2812 (12.8%)	3655 (18.4%)	–
Cardiovascular atherosclerotic disease	2748 (53.2%)	3941 (47.8%)	–
Discharge diagnosis			
Acute myocardial infarction	3009 (1.4%)	3941 (0.7%)	0.005
Coronary heart disease	3009 (11.2%)	3941 (10.9%)	0.721
Heart failure	3009 (4.7%)	3941 (10.0%)	< 0.001
Cerebrovascular disease	3009 (15.2%)	3941 (18.5%)	< 0.001
Peripheral artery disease	3009 (3.8%)	3941 (4.0%)	0.716
Ad hoc criteria			
Arterial hypertension§	2926 (79.5%)	3839 (76.1%)	< 0.001
Dyslipidemia§§	3009 (24.4%)	3941 (23.1%)	0.217
Diabetes§§§	2880 (27.5%)	3836 (25.8%)	0.125

* diagnostic criteria not entirely comparable between the two studies; § blood pressure ≥ 140 mmHg for systolic or ≥ 90 mmHg for diastolic or use of antihypertensive drugs; §§ total cholesterol > 250 mg/dl or HDL cholesterol < 35 mg/dl or triglycerides > 200 mg/dl or use of hypolipidemic drugs; §§§ blood glucose > 126 mg/dl or use of antidiabetic drugs.

The use of antihypertensive drugs among hypertensives defined by *ad hoc* criteria is given in figure 2. There was a slight increase in the proportion of treated hypertensives (significant among men). Even in this subgroup we found, as in the overall patient group, a reduction in the use of ACE-inhibitors balanced by an increase in the use of angiotensin II antagonists, an increase in the use of beta- and alpha-blockers and a stable use of calcium antagonists. All differences were statistically significant except those for calcium antagonists (in both genders) and the general use of antihypertensive drugs among women.

A similar analysis is reported in figure 3 for the use of hypolipidemic drugs in the groups of dyslipidemic patients (defined by *ad hoc* criteria). A stable or slightly decreased use of fibrates was accompanied by a substantial and statistically significant increase in the use of statins moving from 7-8% in 1996 to 23% in 1999 in both sexes. This influenced the overall use of hypolipidemic drugs increasing from around 10-11 to 25%, in a significant manner.

The use of antihypertensive and hypolipidemic drugs has been computed even for some specific patient categories, i.e. coronary heart disease (clinical criteria), cerebrovascular disease (clinical criteria) and diabetes. The results are reported in table IV on pooled genders. Pooling was necessary due to the limited differences between them. The overall use of antihypertensive drugs was always higher among coronary patients than among cerebrovascular and diabetic patients. In both the cardiovascular groups, however, there was a slight decline in their use between the first and the second survey. Changes in the use of specific drugs between the first and the second study showed the same trends already described for the groups of all patients, of hypertensive patients and of dyslipidemic patients. Even the use of hypolipidemic drugs was more common among cardiovascular patients, mainly among coronary patients. For all the three groups of patients a clearly substantial increment in the use of statins was found when the first survey was compared with the second.

Table III. Mean levels of some cardiovascular risk factors in the two studies among patients aged 35 year or more.

	FAPOI-1 (1996)		FADOI-2 (1999)		p
	No.	Mean ± SD	No.	Mean ± SD	
Men					
Systolic blood pressure (mmHg)	2848	143.1 ± 24.4	3535	141.8 ± 24.0	0.033
Diastolic blood pressure (mmHg)	2863	83.5 ± 12.3	3541	82.8 ± 12.2	0.023
Total cholesterol (mg/dl)	2371	190.8 ± 47.5	3014	185.9 ± 45.6	< 0.001
HDL cholesterol (mg/dl)	1192	43.9 ± 13.5	1699	44.4 ± 13.7	0.331
Non-HDL cholesterol (mg/dl)	1146	150.0 ± 49.8	1633	143.8 ± 46.0	< 0.001
Triglycerides (mg/dl)	2407	134.0 ± 80.3	3106	132.9 ± 85.8	0.627
Blood glucose (mg/dl)	2796	115.2 ± 48.8	3509	116.1 ± 49.9	0.473
Creatinine (mg/l)	2807	1.2 ± 0.8	3528	1.2 ± 0.7	1.000
Smokers (%)	2627	38 ± 0.9	3013	35 ± 0.9	0.021
Women					
Systolic blood pressure (mmHg)	2920	147.9 ± 25.8	3749	144.9 ± 25.1	< 0.001
Diastolic blood pressure (mmHg)	2939	84.7 ± 12.4	3807	83.2 ± 12.4	< 0.001
Total cholesterol (mg/dl)	2494	200.6 ± 48.7	3253	196.3 ± 47.6	< 0.001
HDL cholesterol (mg/dl)	1231	48.1 ± 14.0	1758	48.4 ± 14.7	0.576
Non-HDL cholesterol (mg/dl)	1205	155.8 ± 47.3	1721	151.2 ± 46.8	0.009
Triglycerides (mg/dl)	2498	131.8 ± 75.4	3291	125.9 ± 70.0	0.002
Blood glucose (mg/dl)	2860	120.9 ± 56.3	3769	118.6 ± 53.6	0.090
Creatinine (mg/l)	2890	1.1 ± 0.7	3803	1.0 ± 0.7	< 0.001
Smokers (%)	2597	8 ± 0.5	3301	8 ± 0.5	1.00

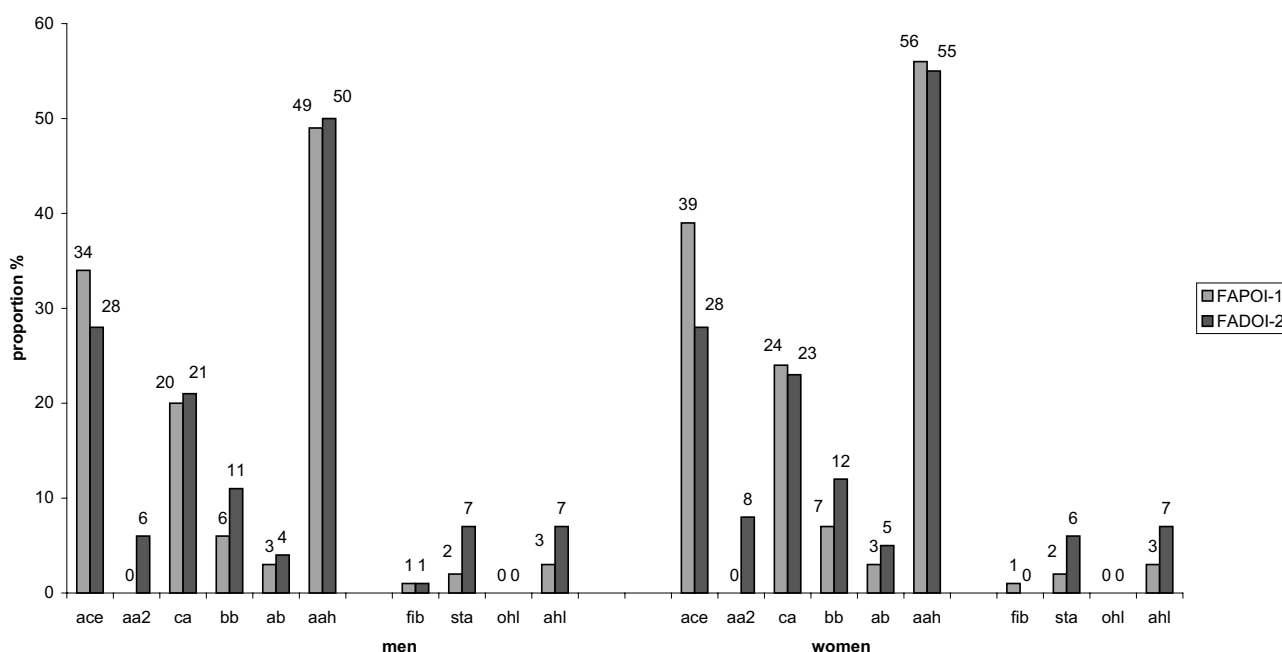Prevalence of smokers in percent and standard error.

Figure 1. *Proportions in the use of specific drugs at the time of discharge in the two studies. Denominators: 2942 men and 3009 women in FAPOI-1; 3676 men and 3941 women in FADOI-2. aa2 = angiotensin II antagonists; aah = all antihypertensive drugs; ab = alpha-blockers; ace = ACE-inhibitors; ahl = all hypolipidemic drugs; bb = beta-blockers; ca = calcium antagonists; fib = fibrates; ohl = other hypolipidemic drugs; sta = statins.*

Discussion

The comparisons made between these two observational studies suggest that, during a 3-year period, the relative frequency of some diseases among patients discharged from Divisions of Internal Medicine in Italy had not substantially changed, confirming the high preponderance of cardiovascular diseases. However, among cardiovascular diseases, a relative increase was recorded for cases of heart failure and cerebrovascular
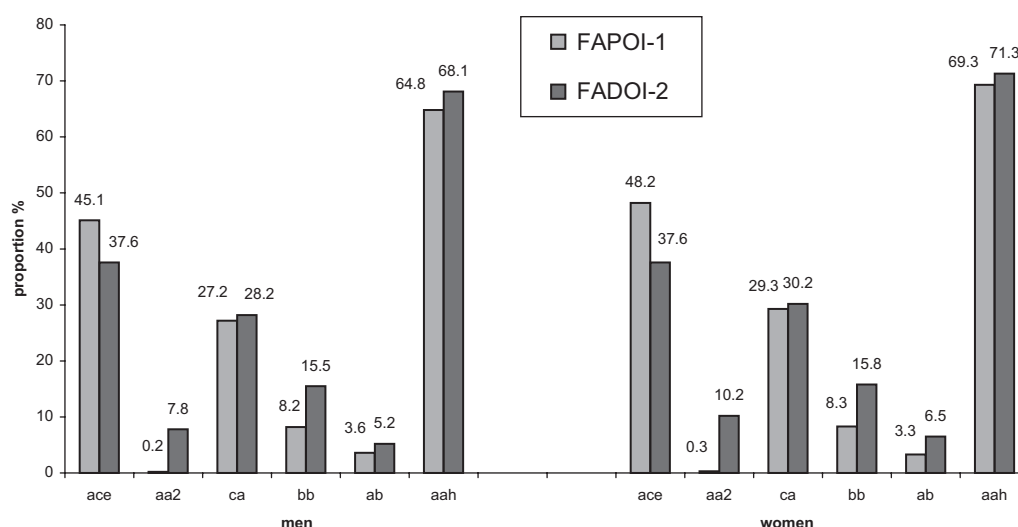
Figure 2. *Proportions in the use of antihypertensive drugs at the time of discharge among hypertensives in the two studies. Denominators: 2208 men and 2410 women in FAPOI-1; 2681 men and 3022 women in FADOI-2. aa2 = angiotensin II antagonists; aah = all antihypertensive drugs; ab = alpha-blockers; ace = ACE-inhibitors; bb = beta-blockers; ca = calcium antagonists.*
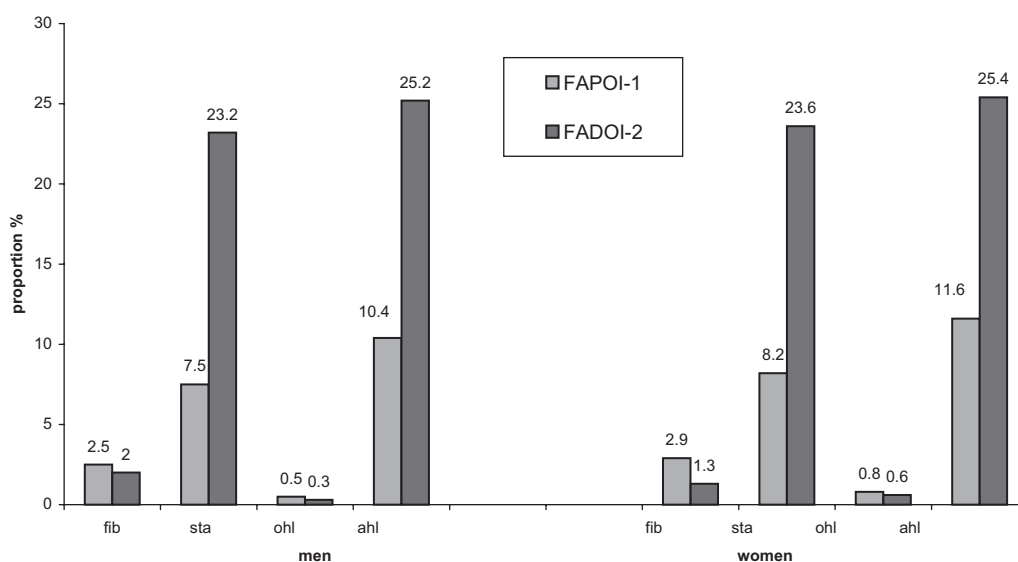

Figure 3. *Proportions in the use of hypolipidemic drugs at the time of discharge among dyslipidemic patients. Denominators: 750 men and 767 women in FAPOI-1; 1034 men and 1016 women in FADOI-2. ahl = all hypolipidemic drugs; fib = fibrates; ohl = other hypolipidemic drugs; sta = statins.*

Table IV. Proportion (%) of antihypertensive and hypolipidemic drugs among patients with diagnosis of coronary heart disease, cerebrovascular disease and diabetes.

	Coronary heart disease		Cerebrovascular disease		Diabetes	
	FAPOI-1	FADOI-2	FAPOI-1	FADOI-2	FAPOI-1	FADOI-2
ACE-inhibitors	53.6	39.6	43.5	30.5	40.8	32.5
Angiotensin II antagonists	0.2	8.4	0.0	6.7	0.1	7.7
Calcium antagonists	30.4	30.1	31.8	32.0	25.0	23.0
Beta-blockers	8.8	17.3	3.7	8.5	5.4	11.3
Alpha-blockers	3.3	5.1	2.9	6.7	3.0	5.3
All antihypertensive drugs	72.2	68.9	62.2	59.4	56.0	56.0
Fibrates	0.6	0.5	0.7	0.4	1.2	0.5
Statins	2.5	8.6	1.1	6.9	2.5	6.6
Other hypolipidemic drugs	0.1	0.1	0.3	0.1	0.3	0.2
All hypolipidemic drugs	3.2	9.1	2.1	7.5	3.9	7.2

disease, although any judgment made regarding these changes should be very cautiously interpreted due to slightly different criteria adopted for the diagnoses.

Apparently, the mean levels of some cardiovascular risk factors were lower in the second compared to the first study, particularly for blood pressure and serum cholesterol and, to some extent, even for the habit of smoking among men.

On the other hand, it is clear that there has been a change in the therapeutic approach to some cardiovascular risk factors which may partially justify their decreasing levels. In particular, we found a decrease in the use of ACE-inhibitors (although still largely prescribed) substituted by angiotensin II antagonists, an increase in the use of beta-blockers and an extraordinary increment in the use of statins. The last finding is, however, still very distant from the maximum potential use of statins, especially when considering the outcomes and suggestions deriving from the most recent clinical trial dealing with this drug class[4]. In general, there were similar changes in the prescription of these drugs, although at different levels, for the overall population of patients, for hypertensive patients, for dyslipidemic patients or for patients with a diagnosis of coronary heart disease, cerebrovascular disease or diabetes.

Comparisons with similar studies specifically conducted in Divisions of Internal Medicine are basically impossible since such studies are not easy to find in the literature. On the other hand, claims about the large potential for a more widespread and deeper intervention on cardiovascular risk factors targeted towards secondary prevention have been recently made by similar studies run on patients carrying specific diagnoses of coronary heart disease. In the EUROASPIRE studies I and II, conducted in 9 and 15 European countries respectively (including Italy), attention was focused on patients with acute coronary manifestations or undergoing coronary surgery, for a total of over 4600 and 8100 patients in the two studies respectively[5-9]. The two studies were run in 1995-1996 and in 1999-2000, that is almost the same dates as the FAPOI-1 and FADOI-2 studies reported here. When comparing findings in the same nine countries participating in both surveys the investigators found, on both occasions, high proportions of cigarette smokers (around 20%), of hypertensives (around 54%) and diabetics (about 20%), a decreasing proportion of patients with high serum cholesterol levels (from 86 to 59%) and an increasing proportion of obese patients. The use of specific drugs was reported to be on the increase between the two studies and within the short-term follow-up of the second study, reaching proportions of 63% for beta-blockers, 38% for ACE-inhibitors, and 61% for lipid-lowering drugs[7-9].

In 1995 a similar study, called MC'95, was independently conducted in Italy enrolling more than 2000 coronary patients in 40 Italian hospitals[10]. At the time of discharge 58% of patients were classified as hypercholesterolemic, 47% as hypertensive, 35% as smokers, 20% as diabetics, and 14% as obese. At the time of discharge from hospital beta-blockers were prescribed to 43% of patients, ACE-inhibitors to 38%, calcium antagonists to 46%, and lipid-lowering drugs to 15%. This study also documented a relatively satisfactory adherence to treatment as judged at the end of a short-term follow-up.

Just as in our two studies, both in the European and the Italian studies information on measurements, diagnoses and drug use was never available for the totality of patients, suggesting that attention for risk factor measurement and control is not universal even in highly specialized settings.

Direct comparisons among the FAPOI-1, FADOI-2 studies[1,2], EUROASPIRE I and II[5-9] and the MC'95 study run in Italy are impossible due to the different age ranges, typology of patients, selection criteria, etc. However, the order of magnitude in the relative proportions of hypertension, diabetes and smoking habits is roughly the same, thus implying that the same kind of problems is found in different clinical settings and different countries. The proportion of dyslipidemia cannot be commented since the criteria adopted in the various studies are too different. The trends in the drug treatment of hypertension and dyslipidemia, when available, are also rather similar across the studies although a much larger use of statins has been recorded in those studies enrolling coronary patients discharged after acute manifestations or coronary surgery. The lesser use of statins and similarly the lesser frequency of dyslipidemia among patients discharged from Divisions of Internal Medicine are partially justified by the typology of patients, since only a small fraction of them were admitted for acute coronary manifestations.

We are aware that the findings of the two FADOI surveys could be overtaken by new situations emerging during the current year. However, plans are in due course to analyze as soon as possible the data from another survey conducted in 2002. On the other hand, comparisons with other more recent studies such as EUROASPIRE II, are not fully pertinent considering the entirely different source of data and medical environment and the different patient selection criteria.

The role of these observational clinical studies seems therefore essential in order to monitor the attention of both physicians and patients to cardiovascular risk factors, their treatment and cardiovascular prevention. Still, there is a considerable potential to further reduce cardiovascular recurrences and to improve the patients' probability of a longer survival. In fact, following the findings of the most recent trial on the role of statins in the secondary and primary prevention of cardiovascular diseases[4], the expectation of a marked decrease in the incidence of major cardiovascular events (roughly estimated at about 25% during a 5-year span) is quite well founded. Of course, the documentation of

such an achievement goes beyond the purpose and the technical possibilities of observational studies whose role remains of interest to check the fall-out of successful clinical trials.

Acknowledgments

Appendix

FAPOI (until May 1998) and FADOI (since June 1998) are the abbreviations of the Federation of the Italian Associations of Hospital Physicians in Internal Medicine.

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