Blood pressure control in Italy: results of recent surveys on hypertension

Massimo Volpe[a,b], Giuliano Tocci[a], Bruno Trimarco[b,c], Enrico Agabiti Rosei[d], Claudio Borghi[e], Ettore Ambrosioni[f], Alessandro Menotti[g], Alberto Zanchetti[h] and Giuseppe Mancia[i]

Background **Blood pressure (BP) control is reported to be poor in hypertensive patients worldwide.**

Objective **BP levels, the rate of BP control, prevalence of risk factors and total cardiovascular risk were assessed in a large cohort of hypertensive patients, derived from recent surveys performed in Italy.**

Methods **Fifteen studies on hypertension, performed in different clinical settings (general population, general clinical practice, specialist outpatient clinics and hypertension centres) over the past decade were considered.**

Results **The overall sample included 52 715 hypertensive patients (26 315 men and 26 410 women, mean age 57.3 ± 6.9 years). Despite the high percentage of patients on stable antihypertensive treatment ($n = 36\,556$, 69%), mean systolic and diastolic BP levels were 147.8 ± 8.5 and 89.5 ± 5.2 mmHg, respectively. On the basis of the nature of the study (population surveys or clinical referrals), systolic BP levels were consistently higher than the normality threshold in both settings (142.6 ± 12.4/84.8 ± 3.7 mmHg and 150.4 ± 4.6/91.9 ± 4.1 mmHg, respectively). The BP stratification could be assessed in 40 829 individuals: 4.5% had optimal, 9.2% normal and 8.3% high-normal BP levels, however, the large majority were in grade 1 (39%) or grades 2–3 (32.6%) hypertension. In the overall sample, 55.9% of hypertensive patients had hypercholesterolemia, 28.7% were smokers, 36.4% were overweight or obese and 15.0% had diabetes mellitus. Cardiovascular risk stratification was assessed in 37 813 hypertensives: 23.2% had low, 33.9% moderate, 30.2% high and 12.7% very high added risk.**

Conclusion **Our analysis demonstrates the persistence of poor BP control and high prevalence of risk factors, supporting the need for more effective, comprehensive and urgent actions to improve the clinical management of hypertension.** ***J Hypertens*** **25:1491–1498 © 2007 Lippincott Williams & Wilkins.**

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[a]Division of Cardiology, II Faculty of Medicine, University of Rome 'La Sapienza' Sant'Andrea Hospital, Rome, [b]IRCCS Neuromed – Pozzilli (IS), [c]Department of Clinical Medicine and Cardiovascular Sciences, University of Naples 'Federico II', Naples, [d]Department of Medical and Surgical Sciences, II Division of Medicine, Azienda Ospedaliera Spedali Civili, Brescia, [e]Division of Internal Medicine, Department of Clinical Medicine and Applied Biotechnology 'D. Campanacci', [f]Division of Internal Medicine Division, University of Bologna, Policlinico Sant'Orsola, Bologna, [g]Association for Cardiac Research, Rome, [h]Centro Auxologico Italiano, and Centro Interuniversitario di Fisiologia Clinica e Ipertensione, IRCCS Ospedale Maggiore, Milan and [i]University of Milano-Bicocca, Ospedale San Gerardo di Monza, Monza, Italy

Correspondence to Massimo Volpe, Division of Cardiology, II Faculty of Medicine, University of Rome 'La Sapienza', Sant'Andrea Hospital, Via di Grottarossa, 1035–9, 00189 Rome, Italy
Tel: +39 06 3377 5561; fax: +39 06 3377 5061;
e-mail: massimo.volpe@uniroma1.it

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Introduction

Observational studies, performed both in western and in developing countries, have shown that prevalence of hypertension is elevated in the general population [1–3], and that control of blood pressure (BP) in the hypertensive population is poor, because in only a small fraction of individuals treated for BP elevation is BP control achieved [4,5]. In European countries, for example, the percentage of patients with BP values less than 140/90 mmHg, as recommended by current international guidelines [6–8], has been reported only in 6–30% of individuals with hypertension [4,5]. This has dramatic consequences for public health, because the benefit of antihypertensive treatment is proportional to the degree of systolic or diastolic BP reduction [8–12], and patients in whom antihypertensive treatment achieves BP levels below 140/90 mmHg are at a lower risk of myocardial infarction, stroke, heart failure, cardiovascular and end-stage renal disease than those remaining above these values [13,14]. An uncontrolled BP leads, in turn, to a higher rate of morbid and fatal events, substantially contributing to the leading position of hypertension as a cause of death worldwide [15,16]. The situation is even more dramatic in perspective,

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because of the continuing increase in the prevalence of hypertension in both western and developing countries [3].

In recent years, many observational studies addressing the issue of BP control have been performed in Italy [17–31]. This gave us the opportunity to achieve a recent appraisal of the control of BP and risk factors in a European country. Therefore, in the present paper, we report the results of a comprehensive analysis of these studies to determine the rate of BP control from quite a large and updated database of hypertensive patients. This analysis, however, also allowed us to obtain large-scale information on two other important issues: (i) the coexistence of hypertension with other risk factors, as well as of the metabolic syndrome and organ damage; (ii) whether the ability to control BP differs between patients followed by general medicine or other levels of care.

Methods

Data search and study selection

We reviewed the medical literature to identify observational clinical studies or surveys, which evaluated the prevalence and clinical characteristics of hypertensive patients in Italy. In this perspective, a computerized literature search was carried out using the Pub-Med, OVID and EMBASE databases, up to April 2006. Those studies clearly defining the presence of a hypertensive population and reporting data on the general characteristics, clinic systolic and diastolic BP levels of the population sample were considered for analysis. According to these criteria, a total of 15 studies were included in the present analysis [17–31]. A list of these studies with acronyms is given in the Acknowledgements section.

Clinic blood pressure values

Although different criteria were used in different studies, BP control was uniformly regarded as a clinic value of less than 140 mmHg for systolic and 90 mmHg for diastolic BP levels. When specific information were available [22–28,30], BP levels were stratified according to the European Society of Hypertension (ESH)/European Society of Cardiology (ESC) guidelines [6], i.e. optimal BP less than 120/80 mmHg, normal BP 120–129/80–84 mmHg, high normal BP 130–139/85–89 mmHg and hypertension (grades 1–3) for values progressively exceeding 140/90 mmHg.

Age, sex distribution, body mass index and cardiovascular risk factors such as smoking, overweight, hypercholesterolemia and diabetes

Overweight was defined as a body mass index (BMI) more than 30 kg/m^2 in one single study as the limit [20], whereas in others BMI cutoff values ranged from more than 25 to more than 27 kg/m^2 [18,23,24,28,29,31]. The presence of hypercholesterolemia was defined on the diagnostic criteria used in the different studies. A serum total cholesterol value exceeding 250 mg/dl was adopted in four studies [20,23,26,29], whereas in other studies the limit was 240 mg/dl [28] or 200 mg/dl [24,30] in one instance, together with a history of the consumption of lipid-lowering drugs [24]. In most studies, the consumption of antidiabetic drugs was used to define the presence of diabetes, in some cases with blood glucose levels exceeding 126 mg/dl [24] or 140 mg/dl [28,31] to prove the diagnosis.

Target organ damage

In most studies, left ventricular hypertrophy was defined by an echocardiographically assessed left ventricular mass indexed to the body surface area greater than 125 g/m^2 in men and 110 g/m^2 in women in most studies [17,20,23,29]. A higher cutoff value (134 g/m^2) was used for men in one study [18], whereas in another [25] left ventricular mass index values greater than 51 g/h$^{2.7}$ in men and 47 g/h$^{2.7}$ in women were used. Carotid atherosclerosis was defined as an average intima–media thickness exceeding 0.8 mm in three studies in which this information was provided [23,25,29], a higher cutoff value (more than 1 mm) being used in another study [18]. In three studies [25,26,29] the presence of microalbuminuria was defined by a urinary albumin excretion rate of between 30 and 300 mg in 24 h.

Cardiovascular risk stratification

The total cardiovascular risk, i.e. the probability of a cardiovascular morbid or fatal event within 10 years, was quantified according to the risk stratification tables of the ESH/ESC guidelines [6]. Accordingly, on the basis of clinic BP values, the concomitance of additional risk factors, the presence of diabetes or organ damage and a history of cardiovascular disease, patients were classified as being at low added risk ($<15\%$ chance of an event), moderate added risk (15–20%), high added risk (20–30%), or very high added risk ($>30\%$).

Data analysis

The main objective of our analysis was to determine the rate of BP control according to the European guidelines [6], i.e. to determine how many patients had BP values less than 140 mmHg for systolic or less than 90 mmHg for diastolic. In this large sample of hypertensive patients in Italy the BP control was also estimated according to the type of studies (population surveys or clinical referrals) and the type of medical assistance (specialist outpatient clinics, hypertension centres or general practitioners) to which patients were referred. Finally, the prevalence of associated risk factors and organ damage was evaluated. Data are expressed as mean $\pm$ SD. Because of the descriptive nature of the results, no statistical test was applied to the data collected.

Table 1 General characteristics of clinical studies on hypertension, performed in Italy during the past decade

Study	Years of observation	Sample size (*N*)	Male (%)	Female (%)	Mean age	BMI	Geographical area	Type of centre	Ref.
Population surveys									
PAMELA	1997–2006	2051	1037 (50.6)	1014 (49.4)	51.0 ± 13.7	25.6 ± 4.4	Monza	DIM	[17]
VOBARNO	1992–2005	225	118 (52.4))	117 (47.6)	57.0 ± 2.0	26.0 ± 3.0	Vobarno	DIM	[18]
GUBBIO	1983–1985; 1991–1992	2570	1125 (43.8)	1445 (56.2)	n.a. (30–79)	27.2 ± 4.4	Umbria	HC	[19]
BRISIGHELLA	1984–1996	940	463 (49.3)	477 (50.7)	58.5 ± 12.4	27.4 ± 3.0	Ravenna	GP	[22]
SMOOTH	2003–2005	4590	2128 (46.4)	2462 (53.6)	60.5 ± 9.4	n.a.	San Marino	GP	[31]
		10 376 (19.7)	4871 (46.9)	5515 (53.1)	56.7 ± 4.1	26.5 ± 0.9			
Clinical referrals									
MAVI	1998 Dec–1999 Dec	1033	396 (38.3)	637 (61.7)	60.0 ± 7.0	27.1 ± 3.7	Italy	HC	[20]
PIUMA	1988–1996	1839	974 (53.0)	865 (47.0)	50.0 ± 12.0	26.7 ± 4.0	Umbria	GP	[21]
APROS	2000 (July–Dec)	1074	570 (53.1)	504 (46.9)	48.1 ± 11.4	26.9 ± 4.7	Italy	HC	[23]
HORIZON	2000 (March–June)	3812	1876 (49.2)	1936 (50.8)	60.1 (45–75)	27.5 ± 4.2	Italy	DIM, DC	[24]
CUSPIDI C	1999 March–2004 July	519	321 (61.8)	198 (38.2)	45.8 ± 11.9	25.4 ± 3.7	Milan	DIM, DC	[25]
OPS	2003 (March–June)	14 513	7530 (51.9)	6983 (48.1)	69.7 ± 6.6	26.9 ± 3.5	Italy	HC	[26]
REACT	2003–2004	1482	790 (53.3)	692 (46.7)	61.8 ± 11.4	27.5 ± 4.4	Italy	HC	[27]
SILVIA	2000 (May–June)	2775	1312 (47.3)	1463 (52.7)	60.6 ± 12.1	n.a.	Italy	DIM, DC	[28]
ETODH	1999–2003 (Jan–July)	2500	1285 (51.4)	1215 (48.6)	53.0 ± 12.6	26.1 ± 4.3	Milan	DIM	[29]
ForLife	2003 (Feb–July)	12 792	6390 (50.0)	6402 (50.0)	66.0 (54–84)	27.2 ± 4.0	Italy	GP	[30]
		42 339 (80.3)	21 444 (50.6)	20 895 (49.4)	57.5 ± 8.0	26.8 ± 0.1			
Total		52 715	26 315 (49.9)	26 410 (50.1)	57.3 ± 6.9	26.7 ± 0.7			

DC, Department of Cardiology; DIM, Department of Internal Medicine; GP, general practitioners; HC, hypertension centre; n.a., not available.

Results

Table 1 reports the main characteristics of the studies analysed, including the type of study, the observational period, sample size, age, sex, BMI, geographical area in the country and type of referral centres. The 15 studies analysed geographically covered the entire Italian territory. Information were collected through different types of studies (population surveys or clinical referrals) and different clinical settings (specialist outpatient clinics, hypertension centres or general practitioners). A total of 52 715 hypertensive patients have been studied in these surveys, of which 26 315 (49.9%) were men and 26 410 (50.1%) were women. The mean age was 57.3 ± 6.9 years, and the mean BMI was 26.7 ± 0.7 kg/m^2.

As shown in Table 2, in the overall population sample mean systolic and diastolic BP levels were 147.8 ± 8.5 and 89.5 ± 5.2 mmHg, respectively. With the exception of the hypertensive population recruited in one study [22], average systolic BP was lower in the hypertensive group of the population surveys than in those recruited in the clinical referral setting. Interestingly, in none of the clinical studies was mean systolic BP below 140 mmHg.

On the basis of data provided by 14 out of 15 studies, approximately one-third of the hypertensive patients were untreated ($n = 14\,508$, 27.5%) and thus approximately two-thirds of hypertensive patients were reported to be under current antihypertensive treatment ($n = 36\,356$, 69.0%). The BP levels were lower in treated than in untreated hypertensive patients (147.3 ± 10.6/87.0 ± 3.6 mmHg versus 148.4 ± 7.4/92.5 ± 4.6 mmHg), the difference being more evident for diastolic than for systolic BP levels.

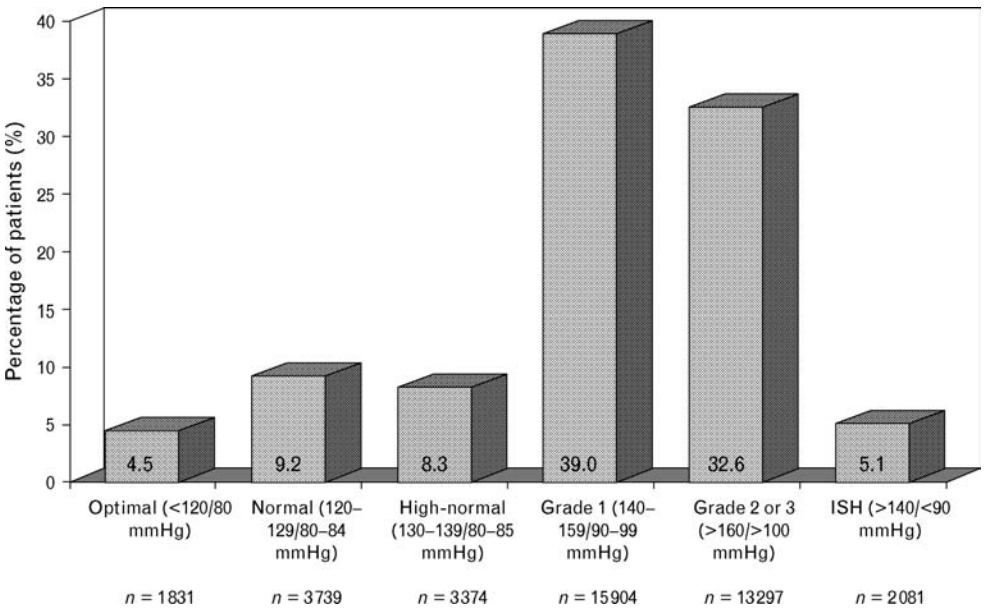
In those studies that reported information on the rate of BP control in the treated hypertensive group, diastolic BP control was achieved in 46.1% ($n = 16\,757$) of the patients, but the rate of systolic BP control was much lower (24.1%, $n = 8761$), and the control of both systolic and diastolic BP was seen in only 17.4% ($n = 6323$). As shown in Fig. 1, among the hypertensive individuals included in studies recently published [17,20,23,25–30], only 4.5 and 9.2% showed BP values in the optimal or normal range, respectively, the remaining 8.3% having high-normal BP levels, in spite of the fact that the large majority of the patients received antihypertensive treatment. In

Table 2 Baseline systolic and diastolic blood pressure levels according to the type of clinical studies, namely population surveys (top) and clinical referrals (bottom), in the overall sample ($n = 52\,715$)

Year of publication	Study	Sample size (*N*)	SBP (mmHg)	DBP (mmHg)
Population surveys				
1997	PAMELA	2051	132.9 ± 21.4	83.9 ± 10.6
1998	VOBARNO	225	138.5 ± 14.0	85.0 ± 8.5
2001	GUBBIO	2570	134.6 ± 21.3	79.2 ± 10.8
2002	BRISIGHELLA	940	163.5 ± 19.0	89.5 ± 12.0
2006	SMOOTH	4590	143.4 ± 15.2	86.3 ± 8.4
		10 376 (19.7)	142.6 ± 12.4	84.8 ± 3.8
Clinical referrals				
2001	MAVI	1033	154.0 ± 18.0	92.0 ± 9.0
2002	PIUMA	1839	156.0 ± 19.0	98.0 ± 10.0
2004	APROS	1074	150.8 ± 10.5	96.3 ± 5.0
2004	HORIZON	3812	154.8 ± 18.2	91.5 ± 9.8
2004	CUSPIDI C	519	146.0 ± 16.5	96.1 ± 7.9
2004	OPS	14 513	153.3 ± 17.8	89.0 ± 9.7
2004	REACT	1482	142.9 ± 16.4	88.4 ± 9.9
2005	SILVIA	2775	145.1 ± 21.6	84.9 ± 12.0
2005	ETODH	2500	147.4 ± 18.0	92.8 ± 9.8
2005	ForLife	12 792	153.6 ± 16.1	89.7 ± 8.9
		42 339 (80.3)	150.4 ± 4.6	91.9 ± 4.1
Total		52 715	147.8 ± 8.5	89.5 ± 5.2

DBP, Diastolic blood pressure; SBP, systolic blood pressure.

Fig. 1



Blood pressure stratification, according to European Society of Hypertension/European Society of Cardiology guidelines [6], in the recently published studies [17,20,23,25–30] ($n = 40\,829$).

contrast, approximately 40% of hypertensive patients with uncontrolled BP levels had grade 1 hypertension, almost one-third being in grade 2 or 3 hypertension. Data on BP stratification in untreated hypertensive patients were specifically reported in only two studies [17,30], and thus are not discussed.

With regard to the type of clinical setting, a smaller proportion of hypertensive patients (approximately 18%) was recruited from specialist outpatient clinics belonging to hospital departments of internal medicine and cardiology (with a much lower representation of other specialistic areas), whereas approximately 44 and 38% patients were followed by hypertension centres or by general practitioners, respectively. As shown in Fig. 2, systolic and diastolic BP values appeared to be less controlled in patients seen by general practitioners, compared with those recruited in hypertension centres and hospital departments of internal medicine and cardiology, although differences were rather small.

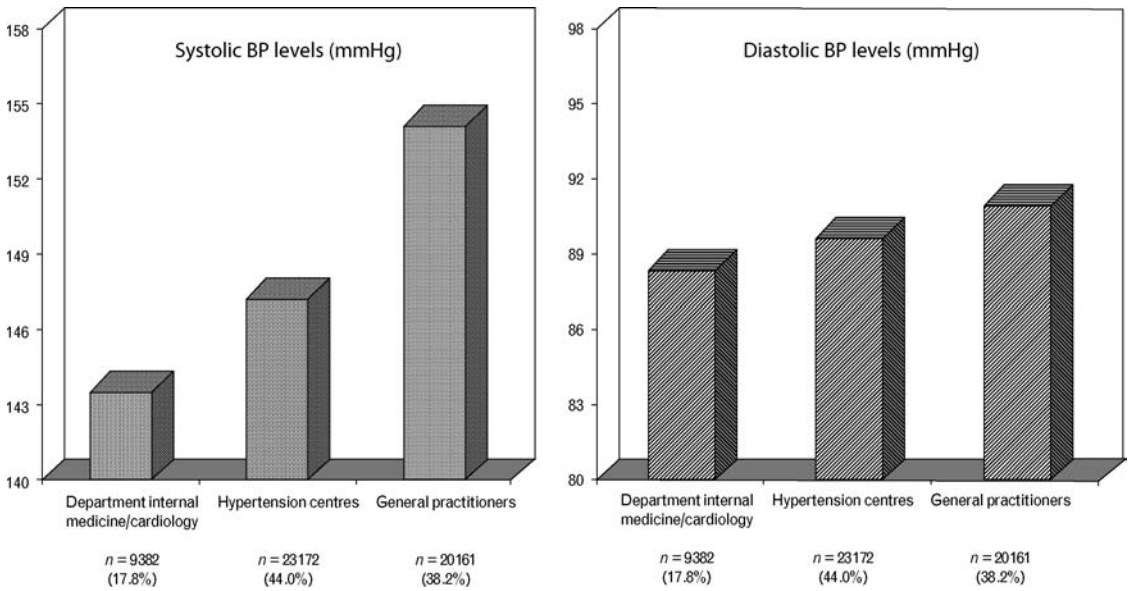
The prevalence of concomitant cardiovascular risk factors is illustrated in Fig. 3. In the overall sample, approximately one-third of patients were smokers, overweight or obese, whereas more than half had hypercholesterolemia and 15.0% had diabetes mellitus. The presence of metabolic syndrome, as defined by the National Cholesterol Education Program Adult Treatment Panel III diagnostic criteria [32], was reported in 4630 hypertensive patients from a total of 22 122 patients (20.9%), recruited in the most recent studies [25,28,29,31]. Echocardiographic left ventricular hypertrophy was reported in 28% of 36 219 patients, in which this marker of target organ damage was investigated by this technique [17,18,20,23,25,27,28, 30,31]. The presence of intima–media thickness or carotid plaques and MAU was assessed in only four studies [18,25,26,29] ($n = 4726$). Although the limited size of the sample is poorly informative, these indices of target organ damage were reported in 43.2% ($n = 1.847$), 33.0% ($n = 1.409$) and 12.8% ($n = 548$) of the hypertensive cohorts, respectively.

Finally, as shown in Fig. 4, in the numerous studies in which global cardiovascular risk stratification was available [22–28,30] ($n = 37\,813$), 8782 (23.2%), 12 819 (33.9%), 11 416 (30.2%) and 4787 (12.7%) patients had low, moderate, high and very high added risk, respectively.

Discussion

The present analysis provides one of the largest available databases in Italy and worldwide on the extent to which BP is controlled by treatment in hypertensive patients or the hypertensive fraction of the general population. The most striking finding of our study is that the control of BP by treatment, namely BP values less than 140/90 mmHg, is achieved in only a small fraction of hypertensive individuals, this also being the case for data collected in the most recent years. BP control is much less frequently achieved for systolic than for diastolic values. In addition, out of the small number of treated hypertensive patients achieving control (20%), only approximately 50% exhibit

Fig. 2

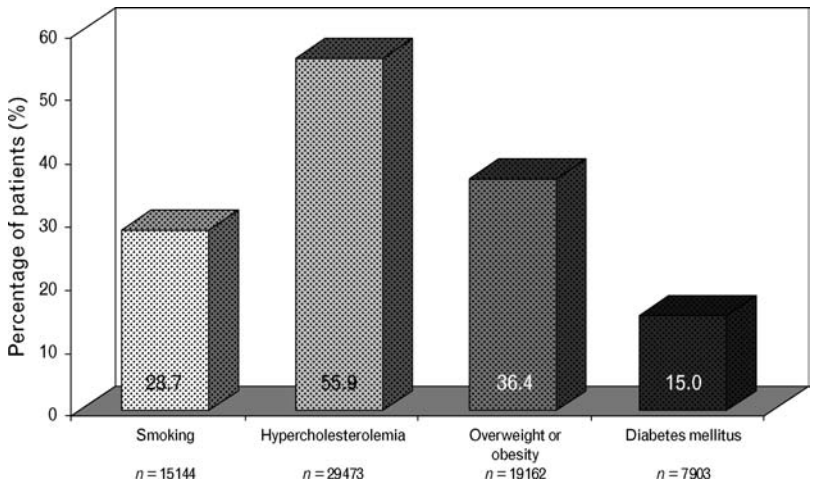


Baseline blood pressure (BP) levels according to the type of referring centres in the overall sample ($n = 52\,715$).

optimal or normal values, the others remaining in the high normal range. Conversely, out of the much greater percentage of treated patients in whom control is not achieved, a substantial fraction (approximately one-third) remains in grades 2 or 3 hypertension, thereby exhibiting BP values much higher than the threshold adopted to distinguish hypertension from normotension.

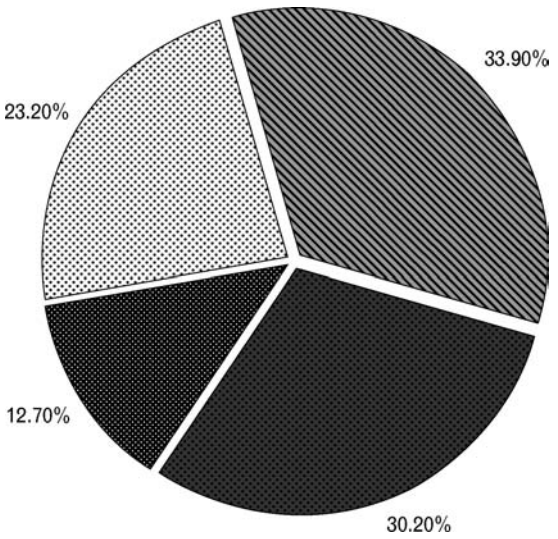
This caused us to conclude that in Italy the effective treatment of hypertension continues to remain largely unsuccessful, because the overall percentage of treated hypertensive patients is small, and many hypertensive patients are not just barely but badly uncontrolled. Furthermore, a substantial fraction of the few hypertensive individuals in whom BP is controlled falls within the high-normal range, thereby failing to achieve the optimal or normal range characterized by a lower cardiovascular risk profile. In line with other studies [4,5], as well as in our analysis, the achievement of systolic BP control by treatment is definitely less common than diastolic BP control, once again emphasizing that the effective reduction of systolic BP values remains a major

Fig. 3



Prevalence of cardiovascular risk factors in the overall sample ($n = 52\,715$).

Fig. 4



Global cardiovascular risk stratification according to European Society of Hypertension/European Society of Cardiology guidelines [6], in hypertensive patients analysed in the most recent studies [22–28,30] ($n = 37\,813$). ▨ Low risk; ▨ moderate risk; ▨ high risk; ■ very high risk.

unfulfilled goal. This is not only the case in the clinical practice setting, but also in trials; that is under conditions in which treatment is administered by expert physicians to motivated patients, systolic BP control is achieved far less than the control of diastolic BP [5]. This greater difficulty in effectively lowering systolic BP calls for further research and clinical efforts focused on this specific issue.

Several other aspects of our present analysis deserve to be discussed. First, data included in the analysis were collected over the entire Italian territory, which means that the conclusion on the unsatisfactory rate of BP control reflects the overall situation in the country. This implies a specific and disappointing element of interest because Italy has a public healthcare system that fully covers the diagnosis and treatment of diseases at small or no cost to virtually all citizens. In addition, in our country the scientific and clinical alert on hypertension and its clinical sequelae goes back decades, because of a large number of highly active scientific societies focused on hypertension and preventive cardiovascular medicine. Second, the control of BP in treated hypertensive individuals was comparable in population surveys and a hypertensive patient-based study, validating the latter as representative of the real situation. Finally, a considerable proportion of the hypertensive patients seen in the studies examined did not have treatment, which indicates that, in addition to a lack of effective BP control, the problem also lays in poor awareness of the hypertensive condition as well as in a failure to start treatment appropriately. Whether this occurs because of patients' unwillingness, physicians' inertia, or bureaucratic difficulties inherent to the healthcare system organization remains to be clarified. Whatever the case, these data clearly show that antihypertensive drugs are not given too much as politicians continuously claim, and that the use of antihypertensive drugs may actually need to be implemented. Another intriguing aspect of our findings is that BP control was somewhat better in patients seen by specialists than by general practitioners, despite the fact that the former were presumably more complicated and thus more difficult to treat effectively. Although the results obtained in the hypertension centres were not as good as one might have expected, this trend implies that acting on physicians' information and motivation and treatment approach holds promise of an improvement.

Our results confirm that in Italy hypertension also rarely comes as an isolated risk factor, as shown in other observational studies [33]. In this regard, approximately half of the hypertensive patients in the present analysis had at least one additional risk factor, abnormalities of the glucose profile and lipid profile as well as overweight or obesity being the most common modifiable ones. Furthermore, 15% of the patients had diabetes mellitus and many showed evidence of the metabolic syndrome; for example, the clustering of alterations in body weight, glucose metabolism and lipid metabolism, strongly predisposing to the development of diabetes mellitus [32]. Finally, approximately one-fifth exhibited organ damage, mostly left ventricular hypertrophy, with more than 40% being classified as having a high or very high added cardiovascular risk according to the ESH/ESC guidelines [6] or World Health Organization/International Society of Hypertension [7] definition. This means that the possibility of a high-risk condition in hypertensive patients seen in clinical practice should not be lightly dismissed. It also implies that the search for associated risk factors as well as for subclinical organ damage should be substantially implemented. It finally means that efforts to control BP rigorously should be even more stringent because of the greater event-saving effect of BP control when the cardiovascular risk is high.

The implications of our findings for the Italian public health system and possibly for other countries are obvious. Evidence is available that hypertension is a major risk factor for a number of cardiovascular diseases [13], has a high prevalence in the population [1–3], and is thus responsible for a large number of cardiovascular fatal and non-fatal events occurring in the population [9–12]. It is also widely recognized that, regardless of the type of treatment, reductions in BP protect against cardiovascular diseases [12,34], which are much more frequent in individuals remaining above compared with those achieving BP values of less than 140/90 mmHg by treatment [14–16]. The low rate of BP control reported here must be held responsible of the progressively increasing

number of cardiovascular events as well as of the related costs. This is true, especially when it is considered that our analysis was restricted to individuals for whom hypertension was known, and that undiagnosed hypertension may aggravate these findings. In addition, the elevated prevalence of high-risk individuals in whom BP values much lower than 140/90 mmHg should be achieved, makes the goal of satisfactory BP control even more elusive in the current Italian situation.

Several actions could be undertaken to improve this situation. Among the various potentially effective interventions, some of them, such as the implementation of simplified guidelines for general practitioners and home BP recordings, may represent simple and relatively inexpensive measures that may contribute to ameliorate BP control in the population.

In conclusion, our analysis of a large representative sample of hypertensive patients derived from the most recent observational studies completed in Italy over the past decade, further confirms a low rate of BP control and cardiovascular risk factors. Our current analysis has major implications for public health, because of the severe impact of uncontrolled BP levels on cardiovascular diseases, in terms of morbidity, mortality and socio-economic burden. More effective and comprehensive actions to control BP in hypertensive patients should be undertaken urgently.

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There are no conflicts of interest.

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