

ORIGINAL ARTICLE

Aggressive blood pressure control in general practice (ABC-GP) study: can the new targets be reached?

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Based on outcome trials, guidelines for hypertension management recommend lower blood pressure (BP) goals using an individualized treatment strategy (IND) and referral to a specialist of patients uncontrolled after 6 months of treatment. This study aimed to evaluate the performance of General Practitioners (GPs) in reaching the recommended BP goals using the IND, or a stepwise treatment strategy (STEP) as used in the outcome trials. Trained GPs were randomized to reach the BP goals within 6 months using the IND or a STEP strategy in untreated or treated uncontrolled hypertensives. In all, 24 GPs recruited 528 patients of whom 443 were analysed (mean age 65 ± 9 years, 42% men, 70% treated, STEP/IND 12/12 GPs, 231/211 patients). After 6 months, 83% of the patients had reached the diastolic BP goal, whereas only 51% the systolic ($P < 0.0001$ for difference).

Factors associated with uncontrolled systolic BP were diabetes, age > 60 years and triple antihypertensive therapy at baseline. A faster BP reduction was achieved during the first 3 months using the STEP strategy, but at the cost of using more drugs (combination therapy in 68/59% for STEP/IND, $P = 0.06$). At 6 months similar rates of control were achieved with the two strategies. In conclusion, in primary care the diastolic BP goal can be reached within 6 months in the majority of patients, whereas systolic BP remains uncontrolled in 50% of the cases. The IND should be the recommended treatment strategy, but further investigation is required on the reasons for treatment failure and the optimal strategy for its improvement.

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Introduction

One of the major issues in hypertension management is the low level of blood pressure (BP) control in the population.¹ Surveys in several countries have shown poor hypertension control with only 6–27% of hypertensive patients having a BP of $< 140/90$ mmHg.^{2–4} On the other hand, recent outcome studies have shown additional benefits in cardiovascular protection by aggressive lowering of BP in hypertensive subjects.^{5,6} The Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-VI)¹ and the International Society of Hypertension-World Health Organization (ISH-WHO)⁷ recommended lower BP goals to be reached in clinical practice. According to the ISH-WHO guidelines, if control of BP has not been reached within 6 months, the physician should

consider referral of patients to a hypertension specialist.⁷

Virtually all the recent outcome trials in hypertension, which showed the benefits of more aggressive antihypertensive drug treatment^{5,6} or compared new vs old antihypertensive drug classes,^{8–13} have used a strict stepwise add-on treatment strategy (STEP). In contrast, the JNC-VI,¹ the ISH-WHO,⁷ the British¹⁴ and the Canadian Hypertension Society,¹⁵ all recommend the use of an individualized treatment strategy (IND), which allows for substitution of drugs that seem to be ineffective in individual patients. It could be argued that BP control may be achieved faster using the STEP compared to using the IND strategy. However, more drugs may be needed using the STEP strategy because it allows for substitution only in the presence of adverse reactions.

The present study was designed (a) to evaluate the performance of General Practitioners (GPs) in reaching the recommended BP goals in primary care and (b) to test the hypothesis that the IND strategy may be inferior in achieving BP control within 6 months, compared to a strict STEP strategy as used in the outcome studies.

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Subjects and methods

Physicians and patients

GPs employed in primary care in rural areas of Greece were invited to participate in the study and to recruit subjects with essential hypertension, men and women, aged 30–80 years. Untreated hypertensives with systolic BP ≥ 150 mmHg and/or diastolic ≥ 95 mmHg on three clinic visits 1–2 weeks apart (two visits in subjects with systolic BP 180–200 mmHg and/or diastolic 105–115 mmHg) were included, as well as treated hypertensives on stable antihypertensive drug treatment (≥ 4 weeks), with systolic BP ≥ 140 mmHg and/or diastolic ≥ 90 mmHg on two clinic visits. Criteria for exclusion were: BP $> 200/115$ mmHg on two succeeding visits during the study, subjects on triple full-dose antihypertensive therapy, heart or renal failure, coronary heart disease, major haematological or pulmonary disease or any other clinically significant illness based upon recent medical history and unwillingness to participate in the study. The study protocol was approved by the Quality Assurance Committee of the Greek Association of General Practitioners. Patients gave informed consent for study participation.

Methods

GPs were trained in hypertension management according to the ISH-WHO guidelines⁷ and were randomized (using computer generated random numbers) to achieve in their patients the new BP goals recommended by the ISH-WHO (systolic/diastolic BP $< 140/90$ mmHg in subjects aged > 65 years and $< 130/85$ mmHg in those < 65 years and in diabetic hypertensives irrespectively of their age) using either the recommended IND strategy^{1,7} or an angiotensin-converting enzyme (ACE) inhibitor-based STEP strategy. All GPs were trained by a hypertension specialist (GS) and two GP tutors (AK and AS) in two 3-h sessions; one in the study protocol and a second in the BP goals and the treatment strategy (IND or STEP strategy according to randomization).

The STEP strategy protocol included the following steps: step 1, medium dose ACE inhibitor fosinopril 20 mg o.d.; step 2, add-on low dose thiazide diuretic chlorthalidone 12.5 mg o.d.; step 3, increase dose of chlorthalidone to 25 mg o.d.; step 4, add-on calcium antagonist amlodipine or felodipine 5 mg, or lacidipine 4 mg, or diltiazem 200 mg o.d.; step 5, increase dose of calcium antagonist (amlodipine or felodipine 10 mg, or lacidipine 6 mg, or diltiazem 300 mg o.d.); step 6, add-on antiadrenergic drug, for example, β -blocker or α_1 blocker or centrally acting agent.

GPs were asked to intensify drug treatment at 2–5 weeks intervals and to provide data on clinic BP and antihypertensive treatment at 3, 6 and 9 months.

With either of the treatment strategies, all drugs were given in a single morning dose.

Clinic BP was measured always by the same GPs for each patient using validated fully automated oscillometric devices (Omron HEM-705CP, Omron Healthcare GmbH, Hamburg; bladder size 12×23 cm or 14×28 cm where appropriate).¹⁶ Triplicate measurements were taken at trough (before drug intake) after 5 min sitting rest and with 1 min between readings. Measurements were taken always on the same arm for each patient and were printed by the device. The average of all the measurements of each visit was used for decision-making regarding study inclusion and treatment titration.

Analysis

Patients with missing follow-up data at both 6 and 9 months were excluded from the analysis. One-way analysis of variance (ANOVA) and Student's *t*-tests were performed for the comparison of multiple or two mean values respectively. Comparison of frequencies was performed using χ^2 tests. Bonferroni's correction for multiple comparisons was applied where appropriate. Univariate correlations were performed between uncontrolled hypertension at 6 months and several demographic characteristics, cardiovascular risk factors, baseline BP and antihypertensive treatment. Variables with a significant univariate association with uncontrolled hypertension were considered in a logistic regression analysis using a forward stepwise selection algorithm in order to identify independent predictors of uncontrolled hypertension. In the multivariable procedure, the presence of uncontrolled hypertension at 6 months was used as the end point and all continuous variables were considered categorically by the application of clinically and statistically appropriate cutoff points. Comparisons and correlations were performed separately for systolic and diastolic BP. A probability value $P < 0.05$ was considered statistically significant.

Results

Physicians and patients

A total of 24 GPs recruited 528 hypertensive subjects (median number of recruited patients per GP was 20, range 9–47) of whom 85 (16%) were excluded because of missing follow-up data at 6 and 9 months. Data from 443 subjects were included in the final analysis. There was no difference between analysed and excluded subjects in regard to age, sex, proportion of diabetics and baseline BP. Baseline characteristics of study participants are presented in Table 1. According to the ISH-WHO guidelines,⁷ 51% of patients should reach a BP goal of $< 130/85$ mmHg and 49% $< 140/90$ mmHg. In 49 patients

(11%) follow-up data were available at 6 but not at 9 months and in 33 (7%) at 9 but not at 6 months.

BP control and drug treatment

There was a large reduction in both systolic (22.9 ± 21.0 mmHg, 95% CI 20.9, 25.1, $P < 0.0001$) and diastolic BP (8.5 ± 11.5 mmHg, 95% CI 7.4, 9.7, $P < 0.0001$) at 3 months (Figure 1). A significant further decline was observed at 6 months (5.4 ± 16.3 mmHg, 95% CI 3.8, 7.0, $P < 0.0001$ for systolic and 1.4 ± 9.2 , 95% CI 0.3, 2.3, $P = 0.001$ for diastolic BP), whereas there was no change in BP between months 6 and 9 (-0.8 ± 13.9 mmHg, 95% CI -2.0 , 0.3 for systolic and 0.1 ± 7.6 mmHg, 95% CI -0.6 , 0.9 for diastolic BP) (Figure 1).

At 6 months, 84% of the participants had reached the diastolic BP goal and only 51% the systolic ($P < 0.0001$ for difference in the control of diastolic vs systolic BP). No further improvement in BP control was achieved at 9 months for both diastolic and systolic BP (83 and 49% of subjects, respectively). The number of drugs given to patients was progressively increased in the course of the study ($P < 0.0001$, Figure 2). Thus, the proportion of patients receiving monotherapy was reduced to less than half, whereas the proportion of those on three or more drugs was nearly tripled.

Patients with uncontrolled systolic BP at the end of the study were older ($P < 0.05$), had higher baseline systolic BP ($P < 0.05$), were more likely to be diabetics ($P < 0.001$) and were taking more antihypertensive drugs at baseline and at 6 months ($P < 0.05$) compared to patients with controlled systolic BP. Univariate analysis showed age, diabetes and number of antihypertensive drugs at baseline to be significant predictors of uncontrolled systolic BP at 6 months. Multivariate analysis

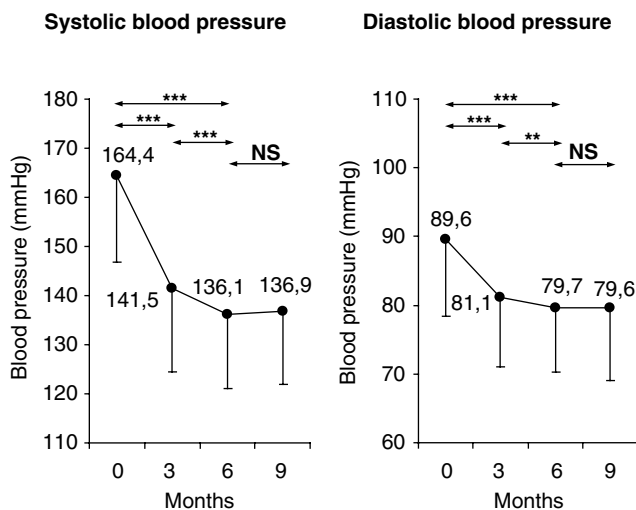


Figure 1 Changes in clinic systolic and diastolic BP during the study. ** $P < 0.01$; *** $P < 0.001$.

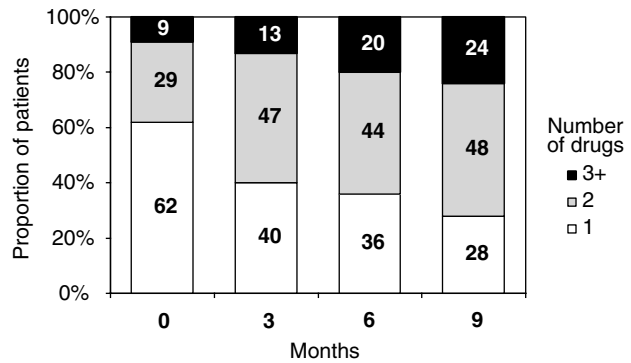


Figure 2 Proportion of treated subjects who received 1, 2 and ≥ 3 antihypertensive drugs during the study.

showed diabetes to be associated with increased risk for uncontrolled systolic BP at 6 months (odds ratio 2.7, 95% CI 1.6, 4.4, $P < 0.001$) as well as age > 60 years (odds ratio 1.7, 95% CI 1.1, 2.7, $P < 0.05$) and triple therapy at baseline (odds ratio 2.6, 95% CI 1.2, 5.7, $P < 0.05$). Regarding diastolic BP, multivariate analysis showed only baseline diastolic BP > 100 mmHg and triple therapy at baseline to be significant predictors of failure to reach the diastolic BP goal at 6 months. Among patients with uncontrolled systolic BP at 6 months, 31% were on antihypertensive monotherapy, 43% on two and 25% on three drugs, compared to 37, 46 and 17%, respectively, among controlled patients ($P < 0.05$).

Individualized vs stepwise treatment strategy

In all, 12 GPs were randomized to use the IND (211 patients) and 12 the STEP strategy (232 patients). Comparison of patients' baseline characteristics in the two groups is presented in Table 1. There was no difference between the two groups regarding patients' body weight at baseline and in the study end. Baseline BP was higher in the STEP compared to the IND group (mean difference 4.7 mmHg, 95% CI 1.5, 8.0, $P < 0.01$ for systolic BP and 2.3, 95% CI 0.3, 4.3, $P < 0.05$ for diastolic) (Table 1, Figure 3). This difference was progressively reduced in the course of the study visits and did not exist after 6 months of treatment (Figure 3).

No differences were found between the two groups regarding the proportion of subjects who reached the BP goal at 6 or 9 months (for systolic BP 54/47% [STEP/IND] of subjects were controlled at 6 months and 48/49% at 9 months; for diastolic BP 86/81% at 6 months and 81/83% at 9 months).

Although at baseline fewer patients were on combination pharmacotherapy in the STEP group (Table 1), there was a tendency for more patients to receive combined pharmacotherapy in this group after 6 and 9 months of treatment, but these differences reached borderline statistical significance at 6 months only (68% in the STEP vs 59%

Table 1 Baseline characteristics of study participants overall and in the individualized and the stepwise treatment strategy groups

	All participants	Individualized treatment strategy	Stepwise treatment strategy	P*
General practitioners	24	12	12	
Patients	443	211 (47.6%)	232 (52.4%)	
Age (years)	64.9 ± 8.9	64.7 ± 8.8	65.1 ± 8.9	NS
BMI (kg/m ²)	28.8 ± 4.7	28.9 ± 5.2	28.6 ± 4.1	NS
Men (%)	42	34	51	<0.001
Diabetics (%)	21	20	23	NS
Untreated hypertensives (%)	30	28	32	NS
Antihypertensive monotherapy (%)	42	38	46	0.01
On ≥ 2 antihypertensive drugs (%)	28	34	22	0.01
Baseline systolic BP (mmHg)	164.3 ± 175	161.9 ± 18.7	166.6 ± 15.9	<0.01
Baseline diastolic BP (mmHg)	89.6 ± 10.7	88.4 ± 11.1	90.7 ± 10.1	<0.05
Target BP < 130/85 mmHg (%)	51	53	50	NS

*Difference between individualized and stepwise treatment strategy groups; BP, blood pressure.

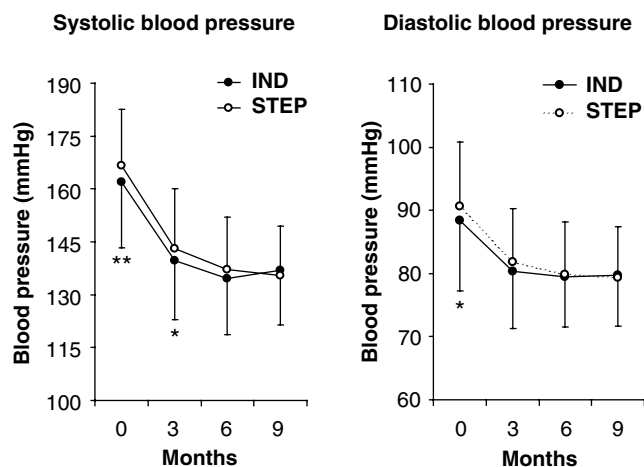


Figure 3 Changes in clinic blood pressure in the individualized (IND) and the stepwise (STEP) treatment strategy group. * $P < 0.05$; ** $P < 0.01$ for differences in BP between the two groups.

and IND group at 6 months ($P = 0.06$) and 75 vs 69% at 9 months respectively [$P = \text{NS}$]). At 6 months 41, 40 and 19% of subjects in the IND group were on 1, 2 and ≥ 3 antihypertensive drugs, respectively, whereas in the STEP group 32, 48 and 20%, respectively. Aggressive pharmacotherapy, defined as the addition of two or more antihypertensive drugs during the study, was more common in the STEP (31%) compared to the IND group (18%) ($P < 0.01$).

Discussion

Since the vast majority of hypertensive subjects are managed in primary care, guidelines for hypertension management should always be tested for their applicability in clinical practice. Therefore, this study provides data on a practical issue, that is

whether it is feasible for GPs to achieve the new BP goals in primary care using the recommended IND strategy. This issue is crucial, first because of the significant improvement in cardiovascular protection which has been shown to be achieved with more aggressive BP lowering^{5,6} and second, because of the known poor level of hypertension control in the population.²⁻⁴

BP control and drug treatment

Effort has been put in the reliable assessment of BP in this study by using validated fully automated devices and by obtaining printout of readings. Therefore, observer bias in BP measurement was largely prevented. Nevertheless, the large BP fall observed during the study cannot be attributed exclusively to drug effects. Several other factors, such as the white coat effect, the placebo effect and the regression to the mean, may also have contributed to BP lowering.¹⁷⁻¹⁹

The most striking finding in this study is that, after 6 months of treatment, the diastolic BP goal has been reached in more than 80% of subjects, whereas in the same time in 50% systolic BP remained uncontrolled. To our knowledge the ABC-GP study is the first prospective study specifically designed to address the feasibility of the new BP goals to be reached in primary care using the recommended IND treatment strategy. The difficulty in controlling systolic BP has been recently suggested by the findings of recent outcome studies using the STEP strategy.^{5,20} In the HOT study,⁵ which was designed to investigate whether more aggressive BP lowering (using a calcium antagonist based STEP strategy) offers additional cardiovascular protection, about 90% of the participants reached a diastolic BP goal of < 90 mmHg, whereas in only 50% systolic BP was reduced to < 140 mmHg. It could be argued, how-

ever, that the HOT study aimed to reach the diastolic BP goal only. In another still ongoing outcome trial aiming to control both systolic and diastolic BP (VALUE),²⁰ similar levels of BP control as in the present study were found (BP control achieved in 90/56% for diastolic/systolic after 12 months of treatment using an angiotensin receptor blocker or a calcium antagonist-based STEP strategy).²⁰

The similarity in the levels of BP control (90/50% for diastolic/systolic) in the HOT, the VALUE and our study is striking and suggests that the effective BP control is not that easy as generally believed and that the difficulty of systolic BP to be reduced to <140 mmHg in real and common. With regard to the ISH-WHO recommendation about the potential for referral of patients with uncontrolled BP after 6 months of treatment, this seems to be unrealistic (impractical and costly) because of the high proportion of subjects with uncontrolled systolic BP.

The failure in achieving a high rate of hypertension control may lead to the conclusion that, simply, 6 or 9 months may be too short period for systolic BP goal to be reached, or that systolic BP may often be resistant to treatment. The absence of a significant improvement in systolic BP control after 6 months despite the fact that patients were receiving more drugs at 9 compared to 6 months (Figure 2) may lead to the conclusion that in many cases once systolic BP is reduced to 150–160 mmHg it may be difficult to achieve further reduction. On the other hand, there is evidence suggesting that primary-care physicians are not aggressive enough in reaching the recommended BP goals.^{21,22} Interestingly, a recent study showed that physicians are often reluctant to increase antihypertensive drug treatment when systolic BP is about 150 mmHg.²³ The findings of the present study showing that, among patients with uncontrolled systolic BP at 6 months, 31% were receiving antihypertensive monotherapy and 43% two drugs, also suggest that the potential of antihypertensive treatment has not been exhausted.

With regard to predictors of poor BP control, our data are in accord with the findings of large studies which have recently shown diabetic hypertensives to be the most resistant to treatment and to require more medication than nondiabetics to reach the BP goal.^{11,12} Increasing age has also been shown to reduce the response to treatment,¹² but, as mentioned above, physicians' attitudes probably also contributed to the failure in controlling systolic BP.²³

Given that only recently emphasis has been placed in the control of systolic BP,²⁴ an important issue to be addressed is how to convince practitioners to push harder in order to achieve tight control of systolic BP. Recently, a joint effort of the American Society of Hypertension and the National Heart, Lung and Blood Institute (NHBLI) has focused on strategies for improving systolic BP control through a continuing medical education Web-cast series.²⁵

Individualized vs stepwise treatment strategy

In order to achieve a high level of compliance of GPs in applying the IND and the STEP strategy, we preferred to avoid their involvement in both the strategies and to randomize GPs rather than patients to the STEP and the IND strategy. Thus, each physician was trained to use only one of the study strategies. However, the randomization procedure failed to include subjects with similar baseline BP levels and antihypertensive treatment in the two groups. This problem, which has been also observed in other larger trials,⁸ is probably attributed to the small number of randomized physicians and to chance, and may have affected the study findings.

Regarding drug treatment, the choice of an ACE inhibitor as initial treatment in the STEP group is supported by the findings of recent outcome trials^{6–10} and is recommended by the ISH-WHO⁷ and the Canadian Society of Hypertension¹⁵ together with other drug options. Provided that there are no compelling indications or contraindications for a specific drug class,^{1,7} the choice of the initial drug does not seem to be so important, given that in order to achieve satisfactory BP control, the majority of hypertensive subjects will require combined therapy with 2–3 drugs.^{5,6,8,9,12}

Although baseline BP was higher in the STEP group, this difference did not exist at 6 and 9 months (Figure 3). The larger BP fall observed in the STEP group suggests that BP control may be achieved faster using this strategy compared to using the recommended IND strategy. However, the tendency for better BP control in the STEP group at 6 months was not evident at 9 months when control rates were identical in the two groups, suggesting that the advantage of the STEP strategy in reducing BP faster does not last longer than a few months. In addition, it should be emphasized that the magnitude of the difference in BP decline between the two strategies was small compared to the large BP decline achieved with both of them.

Since antihypertensive treatment is usually prescribed for lifetime, the use of as few drugs as possible is crucial, provided that satisfactory BP control has been achieved. In this respect, it is important to investigate whether more drugs were required in the STEP group. Although indeed in the STEP group more drugs were prescribed in the course of the study, it should be taken into account that fewer drugs were given in this group at baseline (Table 1).

Nevertheless, given the larger BP fall achieved in the STEP group (Figure 3) these observations do not necessarily mean that more drugs are required using the STEP compared to the IND strategy. Thus, this study cannot definitively prove whether, for the same level of BP reduction, more drugs are needed using the STEP compared to the IND strategy. Taken together these data suggest that the small advantage of the STEP strategy in reducing BP faster may not

be so important. For the physician and the patient, it seems logical to prefer to discontinue ineffective drugs, even at the cost of a relatively longer time until BP control is achieved.

Improvement of hypertension control in the population is expected to have a large impact on cardiovascular morbidity and mortality. Therefore, effective BP control should be the primary goal in the management of hypertension. Primary-care physicians should be informed on the difficulty in controlling systolic BP and the need for combination pharmacotherapy with two or more drugs in the majority of hypertensive patients. The IND should be the recommended treatment strategy, but further investigation is required on the reasons for treatment failure regarding the systolic BP control and the optimal strategy for its improvement.

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Appendix

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