CLINICAL RESEARCH

Effect of an intensive nurse-managed medical care programme on ambulatory blood pressure in hypertensive patients

Effet d'un programme intensif d'éducation thérapeutique infirmier sur la pression artérielle ambulatoire chez des patients hypertendus

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Summary
Background. — Uncontrolled hypertension is a major primary healthcare problem.
Aim. — To investigate whether blood pressure (BP) control in primary care could be improved by nurses taking responsibility for managing hypertensive patients.
Methods. — Randomized trial with two groups: usual or intensive care. Patients diagnosed previously as hypertensive and with a systolic office BP greater than 140 mmHg were randomized to an intensive care programme managed by trained nurses or to usual care. The intensive care programme included a visit every 6 weeks to the general practitioner's office, with standardized BP measurement, self-measurement training, risk factor checks and advice on BP reduction. The intervention lasted for 1 year. The primary endpoints were systolic BP obtained by 24-hour ambulatory BP monitoring after 1 year and the change compared with baseline.
Results. — Two hundred patients from 19 physicians were enrolled (102 in the intensive care group). Data on ambulatory BP were available from 140 patients. Systolic BP declined from

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134.4 ± 14.0 to 126.3 ± 10.4 mmHg in the intensive care group and from 132.4 ± 13.5 to 128.2 ± 13.0 mmHg in the usual care group. There was no statistically significant difference in values after 1 year ($p = 0.332$). The reduction in systolic BP was significantly greater in the intensive care group (7.6 vs 3.3 mmHg in the usual care group; $p = 0.036$). Similar results were observed for diastolic BP and day- and night-time measurements.

Conclusions. — An intensive medical care programme in the office setting managed by trained nurses can improve BP control effectively. Nurses could take more responsibility for managing hypertensive patients.

MOTS CLÉS
Hypertension
artérielle ;
Observance ;
Programme intensif
d'éducation
thérapeutique

Résumé

Justification. — L'hypertension artérielle non contrôlée est un problème majeur de santé publique.

Objectifs. — Nous avons investigué l'hypothèse qu'un meilleur contrôle de la pression artérielle par des infirmières spécialisées en éducation thérapeutique pouvait améliorer la prise en charge des patients hypertendus.

Méthode. — Cette étude randomisée comprenait deux groupes, traitement habituel et traitement intensif de l'hypertension artérielle. Les patients ayant un antécédent d'hypertension artérielle et une pression artérielle systolique en consultation supérieure à 140 mmHg ont été randomisés entre les deux bras, programme intensif et traitement habituel. Le programme intensif était assuré par des infirmières spécialisées et incluait une visite toutes les six semaines au cabinet du médecin généraliste, avec des mesures standards de la pression artérielle, une information et une prise en main de l'automesure, le contrôle de plusieurs facteurs de risque et des conseils sur les modalités de baisse de la pression artérielle. L'étude a duré un an au minimum. Le critère de jugement principal était la détermination de la pression artérielle systolique déterminée par pression artérielle ambulatoire, sur 24 heures, après un an de prise en charge, comparativement aux valeurs à l'état basal.

Résultats. — Deux cents patients traités par 19 médecins ont été inclus dans l'étude, dont 102 dans le bras traitement intensif. Les données sur la pression artérielle ambulatoire étaient disponibles pour 140 patients. La pression artérielle systolique a diminué de 134,4 ± 14,0 à 126,3 ± 10,4 mmHg dans le groupe traitement intensif et de 132,4 ± 13,5 à 128,2 ± 13,0 mmHg dans le bras traitement usuel. Il n'y avait pas de différence statistiquement significative pour les valeurs mesurées à un an ($p = 0,332$). La diminution de la pression artérielle systolique était significativement plus importante dans le groupe traitement intensif, comparativement au groupe traitement usuel (7,6 vs 3,3 mmHg ; $p = 0,036$). Des résultats similaires ont été observés pour la pression artérielle diastolique, ainsi que pour les mesures de pression artérielle en période nocturne.

Conclusion. — Un programme intensif d'éducation thérapeutique assuré par des infirmières spécialisées peut améliorer le contrôle de la pression artérielle chez des patients hypertendus. Les infirmières pourraient prendre plus de responsabilités dans la prise en charge et le traitement des patients hypertendus.

Abreviations

ABPM   ambulatory blood pressure monitoring
BP   blood pressure
GP   general practitioner

Introduction

Hypertension is a major risk factor for cardiovascular and cerebrovascular diseases and a leading cause of mortality worldwide [1]. Lowering blood pressure (BP) with medication and/or lifestyle modifications can reduce substantially the subsequent risks of morbidity and mortality from stroke, heart failure, renal disease and other diseases [2—4]. How-ever, surveys in many countries show that only a portion of patients with hypertension have BP that is within designated levels [5]. A recent survey in the USA and five European countries showed that BP control is best in the USA (63%), whereas in Europe the rates are between 31% and 46% [6]. Therefore, there is much room for further improvement in BP control. It is time for action on BP control as stated in a recent editorial [7]. A cross-sectional survey with general practitioners (GPs) showed that BP less than 140/90 mmHg was achieved in only 42% of patients [8].

Several factors are correlated with inadequate control of elevated BP [9], a key, one of which is therapeutic inertia [10]. Many studies have been published investigating the ability of various programmes to increase adherence to medication and change lifestyle factors. BP measurement

at home, education programmes and nurse management of hypertensive patients have the potential to improve adherence to medication and to increase willingness to modify lifestyle factors [11—23].

Fahey et al. published a review on the effects of various interventions [24], and concluded that a system of regular follow-up should be organized and that the appropriate drug and dosage should be used when patients do not reach the target BP level.

It may well be that strategies have to be individualized to be fully effective [25]. Improving adherence to medication and modification of lifestyle factors are still challenges for physicians and other healthcare providers [26,27]. The time constraints placed on today's primary care physician work force may be one factor that contributes to low control of BP [28].

The aim of this intervention study was to investigate whether the implementation of an intensive medical education programme managed by trained nurses could increase BP control. The intervention combined several methods that have been investigated in different studies: self-monitoring of BP, patient education, nurse management and frequent appointments. The intention was to investigate the effect of this programme, which can be adopted easily into routine practice. Hence we did not implement any monitoring to measure drug adherence, although this method can improve BP control [29]. The integration of nurses into the management of hypertensive patients seems to be a valuable tool in itself [11,30]. However, the effect on ambulatory BP has not been investigated.

Methods

Patients with a prior diagnosis of hypertension and a systolic office BP greater than 140 mmHg were eligible for the study. The participants' systolic and diastolic BP were measured by a trained nurse in the physician's office using a standard protocol and standardized validated automated devices. After a 5-minute rest, seated BP measurements were repeated three times at 2-minute intervals. The third measurement was used as the reference value for study inclusion.

After giving informed consent, all patients received a device for measuring BP at home (Stabil-0-Graph [31]) and were randomized using sealed envelopes to the intensive care programme or to the control group with usual care.

Usual care involved routine visits to the GP's office at least every 6 months, unless there was a specific reason for an earlier visit. All patients in the intensive care programme received a booklet on hypertension [32] and were invited to visit the GP's office at least every 6 weeks for their BP to be measured and to receive individualized advice on how to change lifestyle factors and comply with the prescribed medication. The intervention lasted 1 year and was conducted by nurses trained intensively by one of the authors (MM).

The study was performed in Upper Bavaria in Germany and was approved by the Ethical Committee of the Medical Association of Bavaria.

Primary endpoint

The main outcome was systolic BP assessed by 24-hour ambulatory BP monitoring (ABPM; Mobil O Graph [33]) after 1 year, as well as the change compared with baseline. We used the 24-hour measurements, which are considered to be the gold standard of BP measurement in diagnosis and treatment.

Secondary endpoints

Secondary endpoints were systolic ambulatory BP during the daytime (07:00—22:00) and night-time (22:00—07:00), diastolic ambulatory BP, office BP and change in lifestyle factors (weight, physical activity, tobacco smoking and alcohol consumption).

All variables were measured at baseline and after 1 year. Office BP and lifestyle factors were also recorded after 6 months.

Statistical methods

The data are described as means and standard deviations or numbers and percentages. The primary endpoint (the difference in the change in systolic BP between groups) was analysed by the t-test. The differences within groups were compared by the paired t-test. All other continuous data were analysed in the same way. Qualitative data were compared with the Chi^2 test (between groups) or McNemar's test (within groups). A p-value of 0.05 was considered significant. All analyses were performed with SPSS statistical software, version 15.0.

Sample size calculation

A decline in the office measurement of systolic BP of 10 mmHg corresponds to a change in 24-hour systolic BP of about 7 mmHg [34]. The reduction in the incidence of stroke achieved by a decline in systolic BP of 10 mmHg (office measurement) will be around 35—40%. Our aim was to achieve this reduction in the intervention group. We also expected a reduction in systolic BP in the usual care group of about 3 mmHg, as the result of participation in a study. The trial was designed to have a power of 80% to detect a difference in 24-hour systolic BP between groups of at least 4 mmHg, with a standard deviation of 10 mmHg. This leads to $n = 78$ patients per group. To allow for dropouts, we aimed to enrol about 100 patients per group into the study.

Results

Study population

A total of 19 physicians agreed to participate in this study. Between May 2005 and October 2006, 200 patients were enrolled, 102 into the intensive care group and 98 into the usual care group. The physicians recruited between one and 47 patients. The mean age was approximately 65 years. About half of the patients were men. The mean body mass index was between 29 and 30 kg/m^2, indicating that nearly 50% of patients were obese. About 65% of patients reported

Table 1 Patients' baseline characteristics.

	Intensive care group ($n = 102$)	Usual care group ($n = 98$)	p value
Age (years)	65.8 ± 8.9	65.1 ± 8.5	0.70
Weight (kg)	82.6 ± 15.0	84.2 ± 15.9	0.62
Body mass index (kg/m^2)	29.0 ± 5.2	29.9 ± 5.1	0.13
Physical activity (hours/week)	4.8 ± 6.8	3.6 ± 4.4	0.14
Female sex	42 (41.2)	51 (52.0)	0.12
Smoking status			0.53
Non-smoker	63 (61.8)	69 (70.4)	
Ex-smoker	18 (17.6)	16 (16.3)	
Current smoker	15 (14.7)	9 (9.2)	
Alcohol intake			0.56
No information	2 (2.0)	3 (3.1)	
No alcohol	30 (29.4)	36 (36.7)	
< 1 drink/day	49 (48.0)	38 (38.8)	
≥ 1 drink/day	21 (20.6)	21 (21.4)	
Comorbidities			
Diabetes	21 (20.6)	13 (13.3)	
Myocardial infarction/CHD	6 (5.9)	7 (7.1)	
Peripheral	3 (2.9)	1 (1.0)	
Obstructive arterial disease			
Stroke	2 (2.0)	2 (2.0)	
Chronic obstructive	3 (2.9)	4 (4.1)	
Pulmonary disease			

Data are mean ± standard deviation or number (%). CHD: coronary heart disease.

that they drank alcohol, and 61.8% in the intensive care group and 70.4% in the usual care group were non-smokers. Physical activity amounted to around 4 hours per person per week. Thirty-four patients had diabetes (21 in the intensive care group; 13 in the usual care group) and 13 patients had a history of myocardial infarction. Other comorbidities were reported rarely. There were no significant differences between the groups (Table 1).

Mean systolic BP measured by the trained nurses in the GP's office was 156 mmHg in both groups. Mean diastolic BP was 90.8 mmHg in the intensive care group and 92.7 mmHg in the usual care group. Mean systolic BP measured by 24-hour ABPM (data from 96 patients in the intensive care group and 85 patients in the usual care group were available) was 134.4 mmHg in the intensive care group and 132.4 mmHg in the usual care group; mean diastolic BP measured by 24-

Table 2 Blood pressure at baseline.

	Intensive care group	Usual care group	p value
Office blood pressure (mmHg)	($n = 102$)	($n = 98$)	
Systolic	155.9 ± 11.8	156.3 ± 14.7	0.56
Diastolic	90.8 ± 10.4	92.7 ± 8.6	0.07
Ambulatory blood pressure	($n = 96$)	($n = 85$)	
24 hour			
Systolic	134.4 ± 14.0	132.4 ± 13.5	0.48
Diastolic	80.2 ± 9.7	78.1 ± 8.9	0.10
Daytime[a]			
Systolic	137.7 ± 13.7	135.9 ± 13.5	0.40
Diastolic	82.8 ± 10.2	80.8 ± 9.0	0.10
Night-time[b]			
Systolic	128.7 ± 16.4	126.2 ± 15.9	0.43
Diastolic	75.8 ± 10.1	73.2 ± 10.2	0.08

Data are mean ± standard deviation.
[a] Daytime is 7:00—22:00.
[b] Night-time is 22:00—07:00.

Table 3 Blood pressure after 1 year and compared with baseline.

	Intensive care group	Usual care group	*p* value
Ambulatory blood pressure (mmHg)	(*n* = 78)	(*n* = 62)	
24 hour			
Systolic	126.3 ± 10.4	128.2 ± 13.0	0.33
Decline	−7.6 ± 11.7	−3.3 ± 12.3	0.036
Diastolic	75.0 ± 7.4	74.4 ± 8.0	0.69
Decline	−5.2 ± 7.2	−2.1 ± 7.1	0.013
Daytime[a]			
Systolic	129.3 ± 10.4	131.3 ± 12.8	0.32
Decline	−8.3 ± 11.5	−4.0 ± 12.5	0.036
Diastolic	77.4 ± 7.9	76.8 ± 8.3	0.68
Decline	−5.5 ± 7.0	−2.5 ± 7.1	0.014
Night-time[b]			
Systolic	121.4 ± 11.6	123.3 ± 14.8	0.41
Decline	−6.4 ± 13.8	−2.1 ± 14.1	0.07
Diastolic	71.0 ± 7.3	70.6 ± 8.7	0.74
Decline	−4.6 ± 8.6	−1.3 ± 8.5	0.028
Office blood pressure	(*n* = 86)	(*n* = 68)	
Systolic	136.6 ± 14.4	140.6 ± 17.7	0.25
Decline	−19.4 ± 16.2	−15.0 ± 20.9	0.08
Diastolic	81.6 ± 8.2	82.5 ± 8.8	0.57
Decline	−8.8 ± 9.2	−9.6 ± 10.5	0.87

Data are mean ± standard deviation.
[a] Daytime is 7:00—22:00.
[b] Night-time is 22:00—07:00.

hour ABPM was 80.2 mmHg in the intensive care group and 78.1 mmHg in the usual care group (Table 2).

Results after 6 months

After 6 months, the patients' BPs were checked by trained nurses in the GP's office and their weights were measured. The nurses also interviewed the patients about their smoking and drinking behaviour and their levels of physical activity, using a standardized questionnaire.

Of the 200 patients, 170 attended the GP's office (95 from the intensive care group and 75 from the usual care group). Systolic BP in the office had dropped significantly (−15.5 ± 17 mmHg in the intensive care group, *p* < 0.001; and −13.3 ± 16.4 mmHg in the usual care group, *p* < 0.001). Diastolic BP also fell significantly in both groups (−7.6 ± 10.5 mmHg in the intensive care group, *p* < 0.001; and −8.3 ± 10.5 mmHg in the usual care group, *p* < 0.001). Weight and time spent on physical activity were almost unchanged. There was a reduction in the percentage of smokers in the intensive care group (from 14.7% to 8.4%).

Results after 1 year

A total of 140 patients (78 in the intensive care group; 62 in the usual care group) provided data on both 24-hour recordings (at baseline and after 1 year).

In both groups, systolic BP declined. In the intensive care group, systolic BP dropped from 133.9 ± 12.9 to 126.3 ± 10.4 mmHg in the usual care group, systolic BP dropped from 131.5 ± 13.9 to 128.2 ± 13.0 mmHg. There was

no significant difference in systolic BP between the two groups (*p* = 0.332). However, the reduction in the intensive care group (−7.6 ± 11.7 mmHg) was statistically significant greater (*p* = 0.036; Table 3) than that in the usual care group (−3.3 ± 12.3 mmHg).

Systolic BP declined in 56 patients from the intensive care group compared with in 32 patients from the usual care group (71.8% vs 51.6%, respectively; *p* = 0.02). The decline depended on the BP level at baseline: the higher the BP at the beginning, the greater the decline (Fig. 1).

Similar results were observed for diastolic BP. Again, in both groups, diastolic BP declined; from 80.2 ± 9.7 to 75.0 ± 7.4 mmHg (reduction: −5.2 ± 7.2 mmHg) in the intensive care group, and from 78.1 ± 8.9 to 74.4 ± 8.0 mmHg (reduction: −2.1 ± 7.1 mmHg) in the usual care group. The difference between the two groups was not statistically significant (*p* = 0.69). However, the change was statistically significant larger in the intensive care group (*p* = 0.013). Similar results were observed for daytime and night-time measurements.

BP measurements in the GP's office also declined in both groups. Systolic BP was reduced by 19.4 mmHg in the intensive care group and 15.0 mmHg in the usual care group. This difference was not significant (*p* = 0.08). The reduction in diastolic BP was 8.8 mmHg in the intensive care group and 9.6 mmHg in the usual care group (*p* = 0.87).

Four risk factors were considered: weight, tobacco smoking, alcohol consumption and physical activity. With respect to weight, no change in either group was observed. There was a slight increase in physical activity by about 1 hour per week in the intensive care group, compared with 0.2 hours
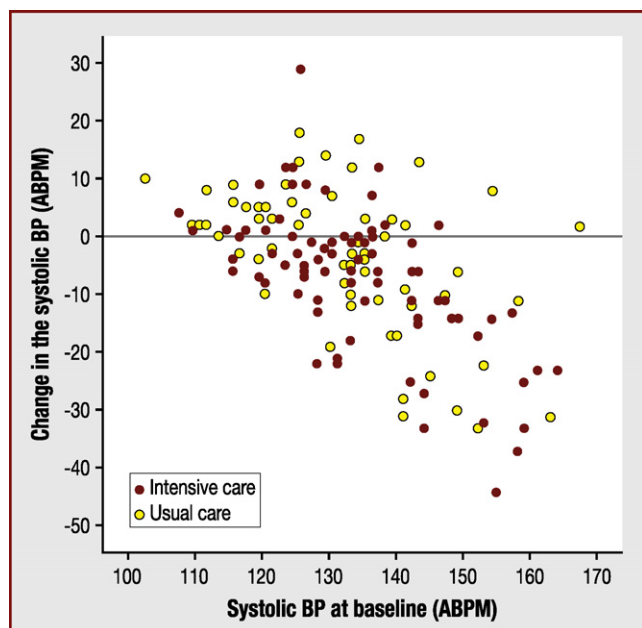
Figure 1. Decline in 24-hour systolic blood pressure in relation to baseline values. ABPM: ambulatory blood pressure monitoring; BP: blood pressure.

per week in the usual care group. In the intensive care group, the percentage of smokers was reduced from 14.7 to 7.0%, compared with a change from 9.2 to 8.8% in the usual care group. In both groups, the percentage of patients who consumed one alcoholic drink or more per day was reduced (Table 4).

Medication

Data about medication staken before entry into the study were available from 167/200 patients (82 in the intensive care group and 85 in the usual care group). Overall, 29 patients had no prescription (16 vs 13 patients, respec-

tively). Of the remaining 138 patients, 59 received only one drug (28 vs 31 patients, respectively). Most of the other patients received two drugs. The drugs prescribed most frequently were angiotensin-converting enzyme inhibitors (81 patients), diuretics (67 patients) and beta-blockers (56 patients). There was no significant difference between groups with respect to the medications prescribed.

At the end of the study, patients were asked about the medication they had taken during the study period. Data from 150 patients were available (78 patients from the intensive care group and 72 patients from the usual care group). Sixteen patients reported that they had not taken any drug (five vs 11 patients, respectively), 44 patients took only one drug (28 vs 16 patients, respectively), 53 patients took two drugs (27 vs 26 patients, respectively). The remaining 37 patients took three or four different drugs (18 vs 19 patients, respectively). The drugs used most frequently were angiotensin-converting enzyme inhibitors (45 vs 36 patients, respectively), followed by diuretics (36 vs 39 patients, respectively)and beta-blockers (31 vs 33 patients, respectively). There were no significant differences between the groups with respect to the medication reported.

Discussion

This randomized study demonstrates that it is possible to improve BP control in the primary care environment by adopting an intensive care programme managed by trained nurses. There was only a small difference between the BP values in the two groups after 1 year. However, the decline in the intensive care group was statistically significant larger, mainly due to the fact that the values at baseline were higher in the intensive care group.

The decline in BP in both groups can be explained by the combination of some of the interventions, home self-monitoring of BP, ABPM and enrolment in the study. The additional decline in BP in the intensive care group can be

Table 4 Patient characteristics after 1 year.

	Intensive care group (n = 86)	Usual care group (n = 68)	p value
Weight (kg)	82.2 ± 15.5	85.0 ± 17.2	0.37
Change	−0.1 ± 2.3	0.1 ± 2.1	0.38
Body mass index (kg/m²)	28.9 ± 5.3	30.2 ± 5.4	0.15
Physical activity (hours/week)	4.5 ± 3.4	3.8 ± 3.5	0.22
Change	0.9 ± 7.0	0.2 ± 3.7	0.92
Smoking status			0.97
No information	10 (11.6)	7 (10.3)	
Non-smoker	61 (70.9)	48 (70.6)	
Ex-smoker	9 (10.5)	7 (10.3)	
Current smoker	6 (7.0)	6 (8.8)	
Alcohol intake			0.84
No information	9 (10.5)	7 (10.3)	
No alcohol	31 (36.0)	26 (38.2)	
< 1 drink/day	30 (34.9)	26 (38.2)	
≥ 1 drink/day	16 (18.6)	9 (13.2)	

Data are mean ± standard deviation or number (%).

explained by the intensive care programme. There was an improvement in three of the four lifestyle factors considered: a reduction in smoking and alcohol consumption, and an increase in physical activity. All changes were small, but may have resulted in a further decline in BP. No change in body weight was observed.

The additional decline in the intensive care group could also be caused in part by an increase in drug adherence. We have data on the medications reported as being taken by the patients but no data on the compliance rate. However, it is plausible that drug adherence did increase, as a result of the intensive education given by the nurses, who continually reminded patients about the need to control their BP in order to minimize the subsequent risk of further diseases.

The decline in office BP was similar to that obtained in a study using electronic monitoring of drug adherence [29]. Therefore, we can assume that the decline in office BP is partly the outcome of an increase in drug adherence.

Strengths and limitations of the study

The advantage of this study was the use of 24-hour ABPM, which gives a better prediction of risk and is superior to office BP measurement [35].

The study had several limitations. The sample size was not very large. Not all the patients could be motivated to provide the 24-hour BP recording at the end of the study. Overall, 78/96 (81.3%) patients in the intensive care group and 62/85 (72.9%) patients in the usual care group attended. Any possible bias should, however, only be small. The response rates were high compared with those in other studies. There were no significant differences in systolic BP values between those patients who provided ABPM measurements at 1 year and those who did not attend.

We did not collect data on compliance. Our primary goal was to reduce BP. Information about compliance would have been desirable, primarily for interpretation, but the effort required to collect reliable data appeared to be too high, and our aim was to show whether BP control is feasible within a programme that can be implemented in routine practice. Patients in both groups received information about BP control, the only difference being that patients in the intervention group had more appointments.

Another problem was the duration of our study, which lasted for 1 year. We obtained no information about a possible long-term effect. In accordance with Haynes et al. [25], who stated that intervention should last forever, our programme ought to be extended.

We could see only a marginal effect on weight reduction. If the programme is going to be implemented in general care, we must increase weight reduction activity.

Comparison with existing literature

This study's findings are consistent with other intervention trials, as reported in several meta-analyses. Mostly, the studies have investigated only one specific intervention, with varying results. The decline in systolic BP was at least 16 mmHg, whereas the decline in our study by office measurement was approximately 19 mmHg.

Implication of further research and clinical practice

It is possible to improve BP control by implementing an intensive care programme conducted by trained nurses and integrated into general care. In our study, an important target was that the interventions should be implemented easily within the GP's daily practice; it aimed to involve the GP only to a small extent. We demonstrated that the intervention selected was effective in reducing BP and was well accepted. A decline in BP was observed in over 70% of the patients.

As the intervention combined several components, it is not possible to identify the separate contribution of each measure; only the total intervention can be judged. The interventions should now be implemented in routine control over a longer period, in order to investigate the long-term effect. More vigorous strategies for weight reduction should be integrated into the intervention program.

This study demonstrates that the treatment of hypertension is still a challenge for physicians, especially given their time constraints.

The decline in the 24-hour systolic BP was in the designated range of approximately 7 mmHg. If this decline could be maintained over a longer period, stroke incidence could be reduced by about 35%. Nurses can play an active role in supervising patients with increased BP, in terms of informing them about the options for changing certain lifestyle factors and helping them to comply with prescribed medication. Nurses can take more responsibility in managing hypertensive patients.

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Conflict of interest

None.

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