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Impact of nurse-mediated management on achieving blood pressure goal levels in primary care: Insights from the Valsartan Intensified Primary carE Reduction of Blood Pressure Study

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Abstract

Background: Blood pressure targets in individuals treated for hypertension in primary care remain difficult to attain.
Aims: To assess the role of practice nurses in facilitating intensive and structured management to achieve ideal BP levels.
Methods: We analysed outcome data from the Valsartan Intensified Primary carE Reduction of Blood Pressure Study. Patients were randomly allocated (2:1) to the study intervention or usual care. Within both groups, a practice nurse mediated the management of blood pressure for 439 patients with endpoint blood pressure data (n=1492). Patient management was categorised as: standard usual care (n=348, 23.3%); practice nurse-mediated usual care (n=156, 10.5%); standard intervention (n=705, 47.3%) and practice nurse-mediated intervention (n=283, 19.0%). Blood pressure goal attainment at 26-week follow-up was then compared.
Results: Mean age was 59.3±12.0 years and 62% were men. Baseline blood pressure was similar in practice nurse-mediated (usual care or intervention) and standard care management patients (150 ± 16/88 ± 11 *vs.* 150 ± 17/89 ± 11 mmHg, respectively). Practice nurse-mediated patients had a stricter blood pressure goal of ⩽125/75 mmHg (33.7% *vs.* 27.3%, p=0.026). Practice nurse-mediated intervention patients achieved the greatest blood pressure falls and the highest level of blood pressure goal attainment (39.2%) compared with standard intervention (35.0%), practice nurse-mediated usual care (32.1%) and standard usual care (25.3%; p<0.001). Practice nurse-mediated intervention patients were almost two-fold more likely to achieve their blood pressure goal compared with standard usual care patients (adjusted odds ratio 1.92, 95% confidence interval 1.32 to 2.78; p=0.001).
Conclusion: There is greater potential to achieve blood pressure targets in primary care with practice nurse-mediated hypertension management.

Keywords

Nurse management, blood pressure, hypertension, primary care

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Introduction

Hypertension is the greatest preventable antecedent to cardiovascular disease (CVD) – the leading cause of death worldwide.[1] In Australia, hypertension affects around one-third of adults,[2] is the most common CVD risk factor managed in primary care[3] and imposes a major cost burden on the health care system.[4] Amid an increasing array of therapeutic strategies, including single-dose combination anti-hypertensive agents, structured advice, monitoring devices and computerised clinical tools,[5,6] there is still a global imperative to address a persistently high proportion of treated hypertensive individuals who do not achieve their blood pressure (BP) goal.[7]

Key barriers to effective BP management and CVD risk reduction in primary care include a lack of time and insufficient resources for primary care physicians to co-ordinate the application of proven therapies with regular and routine follow-up. Alternatively, there is increasing evidence to suggest that nurse-mediated interventions, within a framework of structured care, result in greater reductions in BP levels compared with usual care.[8,9] A pre-specified 'per protocol' analysis of the Valsartan Intensified Primary carE Reduction of Blood Pressure (VIPER-BP) Study,[10] one of the largest randomised trials of BP management to date, provided further evidence that practice nurses (PNs) are pivotal to optimal hypertension management in the primary care setting.[11] Specifically, this pragmatic ideal application of the intensive and structured VIPER-BP intervention (involving a series of clinic visits and intensive up-titration of pharmacological therapy that resulted in significantly improved BP goal achievement relative to usual care) was proportionately better in the presence of a PN.[12]

Study aims

We examined (on a post-hoc basis) the impact of PN-mediated management on BP levels during 26-week follow-up. We hypothesised that exposure to PN-mediated management would be associated with improved BP goal achievement regardless of group assignment to usual care or the study intervention.

Methods

Participants

The rationale, design and pre-specified analyses of the VIPER-BP Study have been published previously.[10] In summary, these analyses explored: 1) early BP control not requiring more intensive management in a sub-set of participants;[13] 2) the overall beneficial effect of the VIPER intervention on an intention-to-treat basis[11] and; 3) the impact of per-protocol adherence on achieving BP goal levels.[12] Briefly, eligible study participants were recruited from over 100 primary care clinics involving more than 250 physicians Australia-wide, if they were aged $\geqslant$ 18 years and diagnosed with hypertension requiring active pharmacological treatment according to Australian expert hypertension guidelines.[14] Individuals with a systolic BP $\geqslant$ 180 mmHg, prescribed $\geqslant$ 3 anti-hypertensive agents, diagnosed with moderate to severe renal dysfunction and/or contra-indications to any anti-hypertensive agents used in the study protocol were excluded.

Study purpose and design

This was a multicentre randomised controlled trial that complied with CONSORT guidelines for pragmatic trials of health service interventions.[15] The VIPER-BP study prospectively tested the hypothesis that a structured and intensive approach to BP management (using a range of valsartan-based anti-hypertensive agents facilitated by a computer-tool to guide up-titration of therapy when required) was superior to usual primary care management in achieving individual BP goal levels during 26-week follow-up.[10]

A broad and representative spectrum of primary care clinics (from small independent clinics to larger practices with shared protocols and governance structures) participated in the study. The primary endpoint of individual BP goal achievement at 26 weeks comprised a lower BP target of $\leqslant$ 125/75 mmHg for those with proteinuria, an intermediate target of $\leqslant$ 130/80 mmHg for those with diabetes or other forms of end-organ damage, and the higher traditional target of $\leqslant$ 140/90 mmHg for all others.[14] The study was approved by relevant ethics committees. A total of 1562 participants with persistent hypertension were randomised into the study, of whom 1492 had outcome data available for endpoint analyses during 26-week follow-up.

Study management

All participants were managed within the Australian universal health insurance scheme (Medicare) that provides reimbursed access (the majority of services without co-payment) to primary care clinics and subsidised pharmacotherapy. Those randomised to the usual care group (n=524) were subject to an enhanced form of routine management with two mandatory visits at six and 26 weeks for BP comparisons. Primary care physicians were asked to manage these participants as they typically would according to Australian guidelines for BP management.[14] Those randomised to the study intervention group (n = 1038) were further randomised at a ratio of 1:2 to commence valsartan monotherapy (160 mg/day) or valsartan combination therapy as a single pill (physician choice of valsartan plus hydrochlorothiazide or amlodipine). Supported by a computerised treatment algorithm tool, the study protocol comprised mandatory visits at weeks six, 10, 14, 18 and 26

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weeks post-randomisation, with the instruction to up-titrate pharmacotherapy if a participant's BP remained above their individual target.

Role of the PN

An increasing feature of Australian primary care is PNs (with a number of government subsidies facilitating their employment). A recent national survey identified an almost 50:50 split in PN responsibilities for clinical versus administrative duties; the latter not routinely involving BP management. As such, a specific role for the PN in applying the study intervention, or even usual care, was not specifically articulated. With few exceptions, however, if a PN was present they often assumed a major role in supporting the study intervention. This involvement was evidenced by: 1) the clinical notes made in case report forms and computerised tool for each study participant and; 2) interaction with the study monitors and data management teams. Overall, 458 individually randomised participants (29.3%) were managed within a clinic where a PN was present. Based on study group allocation (usual care or active intervention) and PN involvement, four specific and mutually exclusive management sub-groups were identified within the study cohort with endpoint BP data (n=1492):

(a) Standard usual care: participants from a primary care clinic *without* a PN and randomised to the *usual care* group (n = 348, 23.3%);
(b) PN-mediated/supported usual care: participants from a clinic *with* a PN and randomised to the *usual care* group (n = 156, 10.5%);
(c) Standard intervention: participants from a clinic *without* a PN and randomised to the *intervention* group (n = 705, 47.3%);
(d) PN-mediated/supported intervention: participants from a clinic *with* a PN and randomised to the *intervention* group (n = 283, 19.0%).

Statistical analyses

This was a post-hoc analysis of study data (intention-to-treat according to study group). Accordingly, comparisons were confined to change in BP levels during 26-week follow-up. The same study data for primary endpoint analyses were used for the current analyses. Where there were missing BP data (e.g. no 26-week clinic visit data) the last known data value was brought forward. Continuous data are presented as a mean (± standard deviation and 95% confidence intervals (CIs) where appropriate) and categorical data as proportions. Baseline comparisons of clinical and demographic profiles were made with Student's t-tests for continuous data and Chi-square test for categorical data. A multiple logistic regression analysis (entry model) adjusting for BP at randomisation and individual BP target was used to determine the independent effect of the four management types in achieving individual BP goal. Comparisons of change in BP levels were made with ANOVA followed by Dunnett's t tests for between-group comparisons. Data were initially prepared and analysed with SPSS v22.

Results

Baseline profile

Table 1 compares the baseline clinical and demographic profile of the overall study cohort according to PN-mediated care within the primary care clinic (439, 29.4%). As originally reported, there was a predominance of men overall (~60%) with around two-thirds receiving ongoing antihypertensive therapy (typically for >5 years). Although the sub-groups were well-matched overall (including baseline BP levels), those exposed to PN-mediated care had proportionately more participants aiming for the most stringent BP goal.

Change in BP levels during 26-week follow-up

Overall, there were significant group differences in respect to average change in all endpoint systolic and diastolic BP values recorded during 26-week follow-up (p<0.001 for overall heterogeneity among 1492 participants). Average BP decreased by 9.5 ± 17.2/5.1 ± 9.8 mmHg in the standard usual care group compared with 11.6 ± 18.2/5.3 ± 11.1 mmHg in the PN-mediated usual care group. By contrast, average BP decreased by 13.7 ± 17.4/8.0 ± 10.4 mmHg and 13.7 ± 17.4/7.4 ± 10.0 mmHg in the standard intervention group and PN-mediated intervention groups, respectively. Consequently, endpoint BP levels recorded during 26-week follow-up were 139 ± 15/82 ± 10; 139 ± 15/83 ± 11; 136 ± 15/81 ± 10 and 135 ± 15/81 ± 10 mm/Hg, respectively. Figure 1 shows the average change in BP levels in each group relative to the standard usual care group (with p values showing difference in BP change relative to this reference group), demonstrating that the greatest changes occurred in the two intervention groups with modest changes in the PN-mediated usual care group.

Achieving BP goals

During 26-week follow-up there were group differences in the achievement of individual BP goals (p<0.001), ranging from 25.3% (88/348) in the standard usual care group to 39.2% (111/283) in the PN-mediated intervention group. A similar but less marked trend (p=0.005) was observed in respect to reaching BP ⩽ 140/90 mmHg. Figure 2 shows these outcomes across all four groups, demonstrating a clear gradient in individual BP goal achievement in favour

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Table 1. Study cohort profile according to PN-mediated care (*N*=1492).

	PN-mediated care	Standard care	*p* value
	n = 439	*n* = 1053	
Socio-demographic profile			
Age, years	58.9 ± 12.0	59.4 ± 11.9	0.468
Men	274 (62.4%)	647 (59.5%)	0.770
Employed	204 (48.2%)	511 (50.0%)	0.564
Non-English speaking background	23 (5.4%)	55 (5.4%)	1.00
⩾ 12 years' education	185 (43.2%)	469 (46.1%)	0.325
Live alone	150 (34.7%)	325 (34.4%)	0.904
Hypertension profile			
Prior treatment	284 (64.7%)	719 (68.3%)	0.183
Years of treatment	*6.1± 8.2*	*6.3 ± 8.4*	0.790
BP at study enrolment	155 ± 13/	154 ± 14/	0.397
92 ± 12	91 ± 11	0.265	
BP at randomisation	150 ± 16/	150 ± 17/	0.924
88 ± 11	89 ± 11	0.996	
Individualised target BP level:			
⩽140/90 mm/Hg	77 (17.5%)	179 (17.0%)	
⩽130/80 mm/Hg	214 (48.7%)	587 (55.7%)	**0.026**
⩽125/75 mm/Hg	148 (33.7%)	154 (27.3%)	
Cardiovascular risk profile			
Total cholesterol, mmol/l	5.3 ± 1.2	5.2 ± 1.1	0.483
Total cholesterol/HDL ratio	4.1 ± 1.4	3.9 ± 1.4	0.116
LDL cholesterol, mmol/l	3.1 ± 1.1	3.0 ± 1.0	0.224
BMI, kg/m^2	30.9 ± 6.4	30.8 ± 6.1	0.763
Obese	234 (53.3%)	562 (53.4%)	1.00
Non-smoker (*n*=1481)	374 (86.0%)	878 (83.9%)	0.344
HbA1c, % (*n*=340)	6.9 ± 1.5	7.2 ± 1.6	**0.047**
Diabetes risk score (*n*=1489)	17.2 ± 5.5	17.2 ± 5.5	0.548
Exercise, h/week (*n*=1376)	4.2 ± 5.2	4.2 ± 5.4	0.866
Depressive symptoms (*n*=1489)	154 (35.1%)	354 (33.7%)	0.632
Absolute CVD risk score, %	14.3 ± 9.2	14.6 ± 9.7	0.548
Clinical profile			
Type 2 diabetes	102 (23.2%)	204 (19.4%)	0.105
Coronary artery disease	40 (9.1%)	84 (8.0%)	0.472
Proteinuria	75 (17.1%)	188 (17.9%)	0.766
eGFR, ml/kg^2	87.2 ± 18.1	88.1 ± 20.2	0.467
Renal dysfunction (*n*=1553)	22 (5.0%)	70 (6.7%)	0.240
Heart rate, beats/min on 12-lead ECG	70.4 ± 11.7	70.4 ± 12.2	0.927
LVH on 12-lead ECG	33 (7.8%)	74 (7.3%)	0.742
Study management			
Usual care	156 (35.5%)	348 (33.0%)	
VIPER-BP intervention			0.627
Initial monotherapy	99 (22.6%)	240 (22.8%)	
Initial combination therapy	184 (41.9%)	465 (44.2%)	

Risk of future diabetes determined by the AUSDRISK score[16] (*n*=1475), depressive symptoms were determined by the two-item Arroll tool,[17] absolute CVD risk score is based on Framingham criteria[18] (*n*=1471), renal dysfunction was defined as an estimated glomerular filtration rate of ⩽60 ml/kg^2 (*n*=1485) and LVH was determined by blinded review of 12-lead ECGs using Minnesota coding criteria[19] (*n*=1403).
PN: practice nurse; BP: blood pressure; HDL: high-density lipoprotein; LDL: low-density lipoprotein; BMI: body mass index; CVD: cardiovascular disease; eGFR: estimated glomerular filtration rate; ECG: electrocardiogram; LVH: left ventricular hypertrophy; VIPER-BP: Valsartan Intensified Primary carE Reduction of Blood Pressure Study.

of PN involvement in both the usual care and intervention groups.

Adjusting for initial BP levels and BP goal targets, there were group differences (p=0.001) in the achievement of the individual BP goal during 26-week follow-up (the VIPER-BP primary endpoint). Relative to standard usual care, the adjusted probability of achieving this endpoint was significantly increased in the standard intervention

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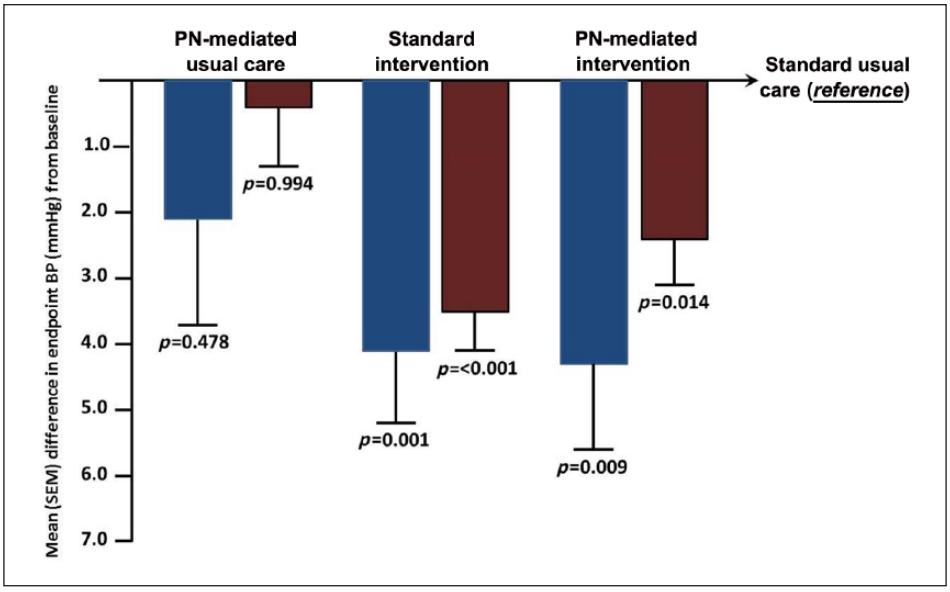

Figure 1. Comparison of average change in systolic blood pressure (blue) and diastolic blood pressure (red) during 26-week follow-up (n=1492) according to type of management relative to standard usual care.
p values reflect the difference in blood pressure (BP) change relative to the reference group (standard usual care). There were no statistical differences in change in systolic or diastolic BP when comparing the practice nurse (PN)-mediated intervention group with the PN-mediated usual care (p=0.81 and p=0.269) and standard intervention groups (p=1.00 and p=0.949), respectively. Data were derived from pre-randomisation and last endpoint BP collected during 26-week follow-up.

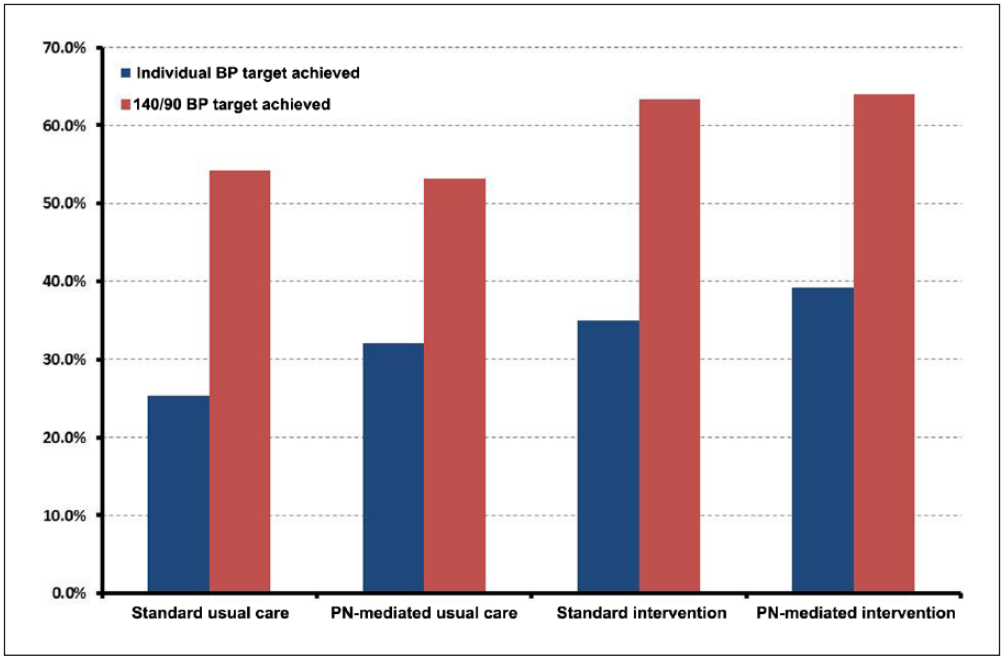

Figure 2. Attainment of blood pressure (BP) control during 26-week follow-up according to type of primary care management.
PN: practice nurse.

group (adjusted odds ratio (OR) 1.74, 95% CI 1.28 to 2.38; p<0.001), with an almost two-fold increase in the PN-mediated intervention group (adjusted OR 1.92, 95% CI 1.32 to 2.78; p=0.001). Exposure to PN-mediated usual care was not significantly associated with an increased likelihood of achieving the individualised BP target goal compared with standard usual care (adjusted OR 1.32, 95% CI 0.84 to 2.09; p=0.233).

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Discussion

The VIPER-BP Study reinforced the potential of structured, intensive hypertension management to improve BP goal achievement in individuals who do not respond to standard primary care management.[11] However, the protocol was not consistently applied[12] and, based on the commonly recommended BP target of 140/90 mmHg, there was still room for improvement. The current analyses demonstrate a clinically significant increase (14% absolute difference) in the proportion of individuals achieving their BP goal within 26 weeks with management that is facilitated by a PN *and* applying a structured, intensive approach to anti-hypertensive management. On an adjusted basis, the latter was associated with an almost two-fold increased probability of achieving individualised BP goals. Similar, but not as favourable, trends for PN-mediated management in BP goal attainment were seen in respect to achieving the historical and less stringent target of ⩽140/90 mmHg.

A contemporary review of studies examining the impact of nurse-mediated interventions on BP goal achievement in primary care concluded that such interventions require a 'structured care' approach to achieve the best outcomes,[8] the latter being the primary focus of the VIPER-BP Study. These findings are in accord with a Cochrane review[9] of the broader literature which suggested that a systematic and structured approach to the management of hypertension in primary care has the ability to reduce BP levels. Consistent with the impact of anti-hypertensive therapy, reductions in BP levels lead to longer-term survival.[20] The review of 33 randomised trials suggested that nurse-led interventions applying a structured approach could achieve an 8 mmHg difference in systolic BP relative to usual care, with community outreach programmes achieving a 1.2-fold increased likelihood of achieving a BP target.[8] As reported in our per protocol analysis of the impact of the VIPER-BP Study intervention,[12] these pooled data are entirely consistent with our finding that, on an adjusted basis, PN-mediated management was associated with a 1.2-fold increased likelihood of achieving an individualised BP target (comprising more stringent BP targets according to the guidelines at the time). Importantly, our current data suggest even greater differences when comparing the impact of physician alone versus PN-mediated BP management. At the very least, we know that PN-mediated management was associated with a greater adherence to pharmacological up-titration and patient attendance to structured visits.[12] There are likely to be other reasons for our findings and these need to be explored on a prospective basis. Moreover, improvements in other cardio-metabolic risk factors, as reflected by gains in absolute risk scores,[11] may have been spurred on by a broader disease management approach. This, however, also needs to be tested further.

As in many other countries, there is an increasing focus on investing in health resources in Australia focused on the prevention of chronic disease within an ageing population. Consistent with this strategy, the PN workforce in primary care continues to expand (7728 in 2007 to 10,693 in 2012).[21] Just under two-thirds of primary care clinics now employ a PN in Australia and around half are actively involved in preventative health assessments/developing chronic disease plans. It has been shown that PNs are often integral to effective communication and organisation of patient care[22] and there is wide recognition that this role needs to be expanded, particularly as they are rarely reported to be actively involved in the management of hypertension. Whilst the precise role of PNs in this study was not formally examined, it may have involved, but not been limited to: organising appointments to see physicians; sending appointment reminder letters; flagging case notes to prompt physician follow-up; taking clinical measurements and informing physicians of any issues identified and; finalising clinical assessments with appropriate follow-up actions.

On this basis, it is worth noting the comparably high rates of BP goal achievement (around the historical target <140/90 mmHg) in the PN-facilitated arm of this study and the much larger community cohort exposed to the Kaiser Permanente hypertension programme in North America,[23] whilst considering key differences in study methods and how BP goal achievement was documented (in the latter study the lowest BP result was used for this purpose). Both programmes applied a systematic and structured approach to BP management and encouraged single-dose combination therapy. In the Kaiser Permanente programme, medical assistants rather than PNs were used to perform follow-up visits and inform primary care physicians of BP values. Consistent with a previous report from the VIPER-BP Study suggesting that primary care physicians with less demanding workloads are more proficient in achieving BP targets,[13] these data suggest that it is the ability of a dedicated health care professional, rather than a particular health discipline, that can best facilitate optimal BP management. Ultimately, the decision to employ additional health personnel to deliver programmes such as the VIPER-BP intervention will likely vary from one health system to another, and perhaps within any one particular health care system depending on associated costs and workforce demands.

At the same time there is a need to invest (in both research and clinical application) in adjunctive strategies to shift what appears to be a very persistent problem in all parts of the globe – treated hypertensive individuals whose BP level remains above their ideal target. At least part of this problem is the phenomenon of prescription resistance by physicians.[24] It is also noteworthy that whilst the difference in absolute BP values between those exposed or not

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exposed to PN-mediated management in the VIPER-BP Study was not large, there was a greater difference in the proportion of people achieving individual BP targets; even when adjusting for a greater proportion of subjects with less stringent BP targets. Underlying any treatment decisions, however, is the following key recommendation, which explicitly underpins the goal of reducing cardiovascular risk in hypertensive individuals and the potential value of the VIPER-BP strategy when mediated by a PN with primary care physician oversight (not necessarily involving direct nurse prescription):

> 'The main objective of hypertension treatment is to attain and maintain goal BP. If goal BP is not reached within a month of treatment, increase the dose of the initial drug or add a second drug…The clinician should continue to assess BP and adjust the treatment regimen until goal BP is reached. If goal BP cannot be reached with 2 drugs, add and titrate a third drug…'.[5]

As discussed, these data represent a post-hoc analysis of the VIPER-BP Study and all data should be interpreted with some caution. Most importantly, whilst PN participation was not formally documented (other than noting their presence in the clinic), it was retrospectively determined from clinical records from the study where the PN commented on BP values and clinical decisions being made in regard to the study protocol. The study was not powered to formally address our underlying hypothesis of greater BP goal achievement associated with PN-mediated management (regardless of study assignment) and we limited our analyses accordingly. It is impossible to comment, therefore, on other important parameters such as lipid control, exercise patterns and diabetes management relative to reducing future cardiovascular risk. As originally reported, a key other study limitation was the self-reporting of BP values by the study teams (albeit subject to clinical monitoring) and we cannot discount systematic bias in reporting by PNs. As emphasised, these data need to be tested properly in a prospective randomised controlled trial with appropriate study power and with blinded end-point adjudication to avoid potential reporting bias. It is also important that the cost–benefits of such an approach be carefully evaluated.

Despite these limitations, these data reinforce the strong potential to enhance the already significant clinical impact of a more structured and intensive (using single-pill combination therapy) approach to BP management in primary care by more actively involving PN participation. At face value these data suggest that PN-mediated management of typically high risk individuals with persistent hypertension has the potential to break through the seemingly unbreakable 'rule of halves' (where 50% of individuals remain uncontrolled despite treatment) and reduce future cardiovascular events in the process.

Implications for practice

- There is a key role for Practice Nurses (PNs) in facilitating a more intensive approach to hypertension management in primary care.
- An integrated approach (supported by PNs), that beyond anti-hypertensive therapy considers ongoing surveillance and intensive up-titration, is proven to assist patients to achieve BP goal levels.
- Better control of BP in primary care requires an electronic clinical profiling and decision support system to identify high risk individuals and then application of a structured treatment programme.
- Continued investment and remuneration for a primary care PN workforce to actively engage in hypertension management is justified.

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Conflict of interest

VIPER-BP was designed by Baker IDI Heart and Diabetes Institute (SS, MJC and GLJ) in consultation with a Scientific Advisory Board (Craig Anderson, JA, Alex Brown, LMB, FJdL, MH (no honorarium), Joseph Hung, Henry Krum, MN, MS, NPS) who received honorarium from Novartis Pharmaceuticals Australia Ltd as study consultants. The sponsors participated in discussions regarding design and conduct of the study and provided logistical support during the trial. Analyses were independently generated by the study statistician (Adrian Esterman, University of South Australia) on behalf of the other members of the Clinical Safety and Efficacy Committee (Colin Johnston, MN, Richard Gerraty). Study data were assessed jointly by the study investigators and the sponsor. All authors have disclosed any conflict(s) of interest and declared that they had a form of support and specific relationships (as described above) with Novartis Pharmaceuticals for the submitted work.

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