IMPPACT: Investigation of Medical Professionals and Patients Achieving Control Together

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OBJECTIVE: To determine whether home blood pressure monitoring (HBPM) led to physician-initiated medication titration and improved achievement of target BP levels compared with standard, office-based management.
METHODS: Physicians were randomly assigned to a treatment group or a control group. Patients in the control group were monitored by their physician and were drug-adjusted according to the usual approach. In the treatment group, patients were given home BP monitors (UA-767P [A&D Medical/Lifesource, USA]), and drug dosing was adjusted according to HBPM readings and protocol. Long-acting diltiazem (240 mg/day) was added at baseline, which was adjusted as necessary (other medications were added if more than 360 mg/day of diltiazem was required). A final BP measurement was taken in the office after six weeks.
RESULTS: Nineteen physicians were randomly assigned to the office BP monitoring group and 34 were assigned to the HBPM group. Of the 270 subjects recruited, 97 were in the office BP monitoring group and 173 were in the HBPM group. From baseline to the final visit, there was a statistically significant time by group interaction with lower BP in the HBPM group (P=0.034 for both systolic BP and diastolic BP). BP fell from 159/91±11/10 mmHg at baseline in the HBPM group to 138/80±13/8 mmHg on the final visit, and from 160/88±14/10 mmHg to 141/78±10/9 mmHg in the control group.
CONCLUSIONS: BP was lowered significantly in both groups, and to a statistically greater degree in the HBPM group. The Hawthorne effect might have led to altered care by the physicians with improvement in BP control in both groups.

Key Words: *Blood pressure monitoring, home; Blood pressure monitoring, office; Hypertension*

IMPPACT : L'exploration des professionnels de la santé et des patients obtenant un contrôle ensemble

OBJECTIF : Déterminer si la surveillance de la tension artérielle à domicile (STAD) a entraîné le titrage de médicaments par les médecins et amélioré le traitement pour obtenir les taux ciblés de TA par rapport à la prise en charge classique en cabinet.
MÉTHODOLOGIE : Les médecins ont été divisés au hasard entre le groupe traité et le groupe témoin. Les patients du groupe témoin étaient surveillés par leur médecin, qui rajustait leur médication de la manière habituelle. Dans le groupe traité, les patients recevaient un tensiomètre portatif (UA-767P [A&D Medical/Lifesource, États-Unis]), et la dose des médicaments était rajustée d'après les lectures et le protocole de la STAD. Du diltiazem à action prolongée (240 mg/jour) était ajouté au départ et rajusté au besoin (d'autres médicaments étaient ajoutés s'il fallait administrer plus de 360 mg/jour de diltiazem). On prenait une dernière mesure de la TA en cabinet au bout de six semaines.
RÉSULTATS : Dix-neuf médecins ont été placés au hasard dans le groupe de surveillance de la TA en cabinet, et 34 dans le groupe de STAD. Des 270 sujets recrutés, 97 faisaient partie du groupe de surveillance de la TA en cabinet et 173, du groupe de STAD. De la première à la dernière visite, on a constaté un temps d'interaction statistiquement significatif par groupe, la TA étant plus basse au sein du groupe de STAD (P=0,034, à la fois pour les TA systolique et diastolique). La TA a chuté de 159/91±11/10 mmHg à la première visite à 138/80±13/8 mmHg à la dernière visite au sein du groupe de STAD, et de 160/88±14/10 mmHg à 141/78±10/9 mmHg au sein du groupe de surveillance de la TA en cabinet.
CONCLUSIONS : La TA a diminué considérablement dans les deux groupes, et à un degré statistiquement significatif dans le groupe de STAD. L'effet Hawthorne peut avoir modifié les soins administrés par les médecins de manière à améliorer le contrôle de la TA dans les deux groupes.

Hypertension affects 22% of Canadian adults and is a major risk factor for stroke, as well as cardiovascular, renal and peripheral vascular disease (1). Each 20 mmHg increase in systolic blood pressure (SBP) or 10 mmHg increase in diastolic blood pressure (DBP) can double the risk of death from stroke and cardiovascular disease (2). Despite the array of treatment options available, including lifestyle modifications and drug therapy, supported by clinical practice recommendations, a recent Canadian study of hypertensive patients found that 84% had uncontrolled BP (3). Engaging patients in the management of their condition with HBPM may lead to better outcomes.

In the past, office BP monitoring (OBPM) has been the most commonly used method of BP monitoring. Recently, however, home BP monitoring (HBPM) has been identified as an acceptable diagnostic method (4) and considered at least as effective as OBPM by clinical guidelines (5). Studies have shown that HBPM measurements are generally lower, more accurate and provide a better prognostic value than OBPM because of the absence of observer bias and the white coat effect (4,6,7). Because of this, it has been recommended that a value of 135/85 mmHg be used as the cut-off value for the diagnosis of uncomplicated hypertension by HBPM, compared with the standard cut-off of 140/90 mmHg by OBPM (5). HBPM provides more BP measurements and gives a reading closer to that obtained by ambulatory BP monitoring (8).

It has been established that both physicians and their patients are more likely to pay greater attention to BP management when attention is specifically aimed at this outcome (such as in taking part in a study). It is interesting that Myers (9) found that when physicians and subjects were aware of a research setting, there was a trend for BP measurements to be lower. Isolating this effect and introducing it into routine practice through the use of HBPM may lead to better long-term control of BP.

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TABLE 1
Treatment algorithm for home blood pressure (BP) monitoring

Average BP	Dose adjustment
Self-monitored systolic BP >136 mmHg *or* diastolic BP >83 mmHg	Increase diltiazem dose to 360 mg daily
Self-monitored systolic BP ≤136 mmHg *or* diastolic ≤83 mmHg *or* average home heart rate <45 beats/min	No increase in diltiazem dose

One avenue likely to procure clinical benefits through the expansion of patient autonomy is the measurement of BP. There is evidence that increases in patients' involvement in their own care, in the case of diabetes, is associated with improved results (10). The direct question is this: will extending patient autonomy through HBPM yield better patient outcomes? The objective of the present study was to determine whether giving HBPM monitors to study subjects leads to improved BP control assessed by OBPM.

METHODS

The Investigation of Medical Professionals and Patients Achieving Control Together (IMPPACT) study was a prospective, six-week, open-label randomized controlled trial evaluating the effects of HBPM on patients compared with no HBPM. The primary outcome was the proportion of patients achieving a target BP lower than 140/90 mmHg. The secondary outcome was the dose of antihypertensive, long-acting diltiazem (Biovail Inc, Canada) used for BP control.

Fifty-three physicians participated in the 42-day trial. Physicians were allocated to either distribute HBPM devices to up to 10 of their hypertensive patients or assign them to usual care. Thirty-four physicians were allocated to the HBPM group and 19 were allocated to the OBPM group. Clustering of physicians in the HBPM group occurred because of multiple physician clinics, where all the physicians participating were given the same allocation. A total of 270 patients were entered in the present study; 173 received HBPM devices and 97 received usual care (control group).

Subjects were recruited by their physician if they were older than 18 years of age, had an SBP of 140 mmHg to 179 mmHg or an DBP of 90 mmHg to 105 mmHg at the time of screening, were currently being treated for hypertension, capable of using the BP monitor and recording measurements and if they gave written consent to participate. Exclusion criteria included secondary hypertension or a recent diagnosis of hypertension, a known intolerance to diltiazem, current use of a calcium channel blocker, a history of acute coronary syndrome, stroke or transient ischemic attack within six months, diabetes mellitus, pregnancy or breastfeeding, severe left ventricular dysfunction, and second or third degree atrioventricular block or sick sinus syndrome.

BP was measured in the physician's office according to the physician's usual practice, with additional instructions to allow the patient to rest in a seated position for a minimum of 5 min before taking two measurements in the same arm, with at least 1 min between measurements. These readings were recorded by the physician and later averaged.

Diltiazem is a nondihydropyridine calcium channel blocker commonly used to treat hypertension and angina. In a large, practice-based, open-label multicentred study (11), a daily dose of up to 360 mg of diltiazem was found to be optimal in terms of control of hypertension and patient compliance. Physicians in both treatment groups were instructed to start and titrate diltiazem, beginning at 240 mg daily at the time of the patient's first study visit for uncontrolled hypertension. This dose was then adjusted as deemed necessary by their physician on each successive visit, to a maximum of 360 mg, at which time other hypertensive medications could be prescribed as necessary. Patients were allowed to remain on their previous medications at the discretion of their physician.

TABLE 2
Patient demographics (n=270)

Demographics	HBPM (n=173)	OBPM (n=97)
Men, n (%)	83 (48.0)	49 (50.5)
Age, years (mean ± SD)	62.6±13.6	63.5±15.1
Smokers, n (%)	43 (24.9)	20 (20.6)
Caucasian*, n (%)	127 (73.4)	89 (91.8)
Body mass index, kg/m^2 (mean ± SD)	31.2±24.1	30.0±6.7
Cardiac conduction disturbance, n (%)	6 (3.5)	2 (2.1)
Cerebrovascular disease/ transient ischemic attack, n (%)	6 (3.5)	4 (4.1)
Coronary artery disease*, n (%)	14 (8.1)	23 (23.7)
Peripheral vascular disease, n (%)	9 (5.2)	10 (10.3)

**P<0.01. HBPM Home blood pressure monitoring; OBPM Office blood pressure monitoring*

At the first visit, patients in both groups were started on diltiazem 240 mg daily. Interim visit(s) occurred at the discretion of the physician and were scheduled at the same time of day to minimize fluctuations in BP. At each visit, patients were reassessed and their doses of diltiazem were adjusted according to the physician's usual practice. At 42±6 days, the final visit was scheduled, and the patient's final BP was measured as described above with a mercury sphygmomanometer in the physician's office.

Patients in the HBPM group were given the UA-767P automated BP device (A&D Medical/Lifesource, USA), along with instructions on how to use the mechanism, at the time of their initial visit. They were instructed to measure and document their BP and heart rate twice daily (one morning and one night-time measurement) on the same arm after 5 min of rest in a seated position. Patients were instructed to return for a follow-up visit between day 14 and day 21, and for a final visit on day 42 (±6 days). During these visits, the physician assessed the patient, and BP was measured in the office with the mercury sphygmomanometer. The dose of diltiazem was adjusted according to a treatment algorithm provided based on the BP recorded at home by the subjects with the HBPM device (Table 1). Other than the BP device, patients were assessed similarly in the control group, but the dose of diltiazem was adjusted based on the OBPM measurement.

Statistical analysis

The study was designed to be capable of detecting an 8% difference in the proportion of patients achieving BP control. Initially, 577 patients in each group were to provide 80% power for α=0.05 and a two-sided χ^2 test (without continuity correction) to detect an 8% difference. However, only 270 patients were recruited and able to complete the study – fewer than one-half the number needed to show the planned difference between groups.

Changes from baseline in BP, heart rate and diltiazem dose by group were analyzed by repeated measures ANOVA. Mean DBP, SBP, heart rate, pulse pressure and diltiazem dose were calculated at the two time intervals (baseline and final). P<0.05 was accepted to be significant.

No effort was made to ensure an equal number of patients per group; some physicians recruited more than others. In addition, as seen in Table 2, there were differences in the subjects between groups. Ethics approval was received from the Institutional Review Board of IRB Services; all participants and physicians were informed about the study and provided written consent.

RESULTS

Three hundred twenty-four patients were recruited for participation – 211 for the HBPM group and 113 for the OBPM group. Inclusion of patients for analysis was limited to those who were able to complete the study (n=270) and 54 patients were unable to complete the study.

TABLE 3
Patient characteristics

Characteristic	Total (n=324)	Included (n=270)	Excluded (n=54)
Men, n (%)	154 (47.5)	132 (48.9)	22 (40.7)
Age, years (mean ± SD)	62.9 (13.7)	62.9 (14.1)	62.8 (11.4)
Smokers, n (%)	71 (21.9)	63 (23.3)	8 (14.8)
Caucasian, n (%)	254 (78.4)	216 (80.0)	38 (70.4)
Body mass index, kg/m^2 (mean ± SD)	29.1±6.4	29.0±6.5	29.6±5.3
Cardiac conduction disturbance, n (%)	10 (3.1)	8 (3.0)	2 (3.7)
Cerebrovascular disease/ transient ischemic attack, n (%)	12 (3.7)	10 (3.7)	2 (3.7)
Coronary artery disease, n (%)	40 (12.3)	37 (13.7)	3 (5.6)
Peripheral vascular disease, n (%)	21 (6.5)	19 (7.0)	2 (3.7)

TABLE 4
Results summary

	HBPM	OBPM
Systolic blood pressure, mmHg (mean ± SD)		
Baseline	159±11	160±14
Final	138±13	141±10
Diastolic blood pressure, mmHg (mean ± SD)		
Baseline	91±10	88±11
Final	80±8	78±10
Heart rate, beats/min (mean ± SD)		
Baseline	76.0±9.6	78.0±10.4
Final	74.8±25.2	80.3±25.2
Diltiazem dose, mg (mean ± SE)		
Baseline	236.5±2.7	238.1±3.7
Final	272.6±2.7	273.4±3.7

HBPM Home blood pressure monitoring; OBMP Office blood pressure monitoring

Demographics of all patients enrolled in the study, as well as a comparison of those who completed and did not complete the study, are found in Table 3. General results of patients are shown in Table 4 and Figures 1 and 2. The characteristics of HBPM and OBPM patients (Table 2) showed significant variability, likely reflecting the differing practice characteristics of the participating physicians, particularly those in multipractice settings. Patients in both treatment groups were permitted to remain on their previous medications (Table 5). Figure 1 demonstrates that SBP fell in both groups from baseline to the final visit (P<0.0001). DBP also fell in both groups from baseline to the final visit (P<0.0001) (Figure 2). The main outcome measure of the study was a time-by-group change in BP; there was a statistically significant time-by-group reduction in BP, such that SBP was lower over time in the HBPM group than in the usual care group (P=0.0034). However, Figure 1 demonstrates that, clinically, this was a very small difference. Heart rate did not show any significant decreases in either group.

Of the 173 patients in the HBPM group, 58.4% achieved SBP control (BP lower than 140 mmHg), 90.8% achieved DBP control (BP lower than 90 mmHg), 57.2% achieved both systolic and diastolic BP control, and 30.6% were titrated to the maximum dose of diltiazem (360 mg). Of the 97 patients participating in the OBPM group, 49.5% achieved SBP control, 92.8% achieved DBP control, 47.4% achieved both systolic and diastolic BP control, and 29.9% reached the maximum dose of diltiazem (360 mg).

DISCUSSION

The objective of the IMPPACT study was to determine whether giving HBPM to patients leads to lower achieved BP. OBPM was used as the standard BP monitoring for the present study, in recognition of the variability of this method. Studies (4,6,7) have demonstrated that measurement of HBPM has a better prognostic value than OBPM, leading to its use as a diagnostic device; however, there is minimal evidence regarding the use of HBPM to direct the treatment of hypertension. Results from the present study did not demonstrate a benefit of HBPM compared with OBPM for lowering BP.

Of interest, BP dropped significantly in both groups, most likely due to the addition of a new antihypertensive drug in both groups, resulting from participation in the study protocol. This reinforces the message that multiple drug therapy is required in most patients. It also demonstrates the impact of raising awareness of BP management. While it is possible that BP also might have fallen between visits just

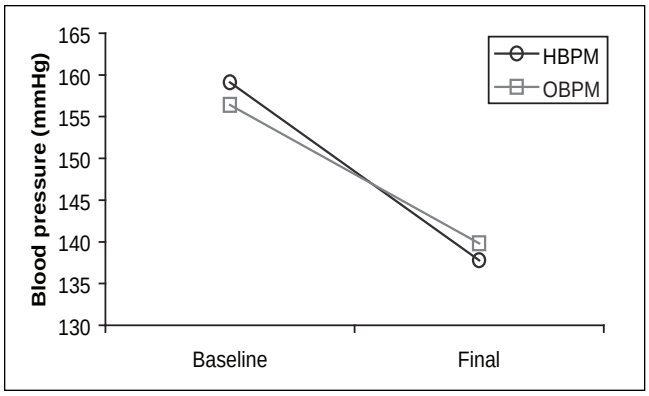

Figure 1) *Systolic blood pressure (BP): home BP monitoring (HBPM) versus office BP monitoring (OBPM) at baseline and on final visit*

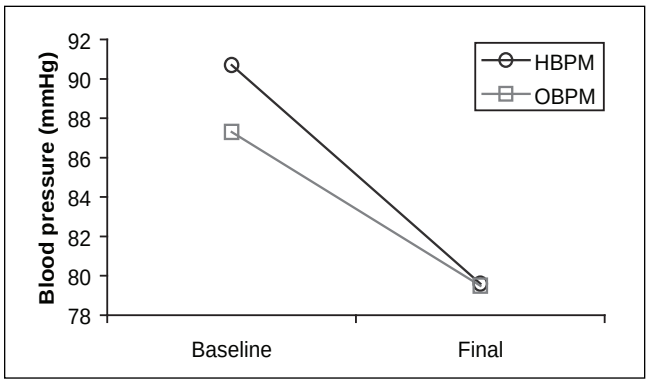

Figure 2) *Diastolic blood pressure (BP): home BP monitoring (HBPM) versus office BP monitoring (OBPM) at baseline and on final visit*

TABLE 5
Concomitant medications

Medication	Included (n=270) Baseline	Included (n=270) Final	Excluded (n=54)
Angiotensin-converting enzyme inhibitor, n (%)	102 (37.8)	100 (37.0)	42 (77.8)
Angiotensin receptor blocker, n (%)	76 (28.1)	70 (25.9)	18 (33.3)
Antiarrhythmic, n (%)	2 (0.74)	4 (1.5)	0 (0)
Acetylsalicylic acid/antiplatelet, n (%)	80 (29.6)	77 (28.5)	32 (59.3)
Dihydropyridine calcium channel blocker, n (%)	8 (3.0)	4 (1.5)	3 (5.6)
Diuretic, n (%)	142 (52.6)	139 (51.5)	32 (59.3)
Statin, n (%)	95 (35.2)	91 (33.7)	20 (37.0)
Other, n (%)	15 (5.6)	19 (7.0)	8 (14.8)

as a normal course of practice, these patients were already well known to the practices.

The Hawthorne effect occurs when individuals alter their behaviour because they are aware of extra attention, such as that received during a research study. Physicians were given detailed instructions on measuring patient BP, as well as instructions on dosing an antihypertensive drug, and information was shared on the importance of BP management. The change in BP in the control group demonstrates the effect on practice from this minimal intervention. This raises the question of which intervention had the greatest effect on physician practice: HBPM or the fact that the physicians were being monitored as part of the study. The parallel reduction in BP in the control group suggests that the latter factor is at play here. We found a similar effect in patients with diabetes and hypertension who were randomly assigned to a control group that had their BP readings sent to their primary care physician by a home care nurse (12). BP fell significantly over the course of the study in the control group as well.

More participants were randomly assigned to the HBPM group than the OBPM group because physicians in several multigroup practices were enrolled into the study, and most of the physicians in the practices given HBPM wanted to participate. In the usual care group, only one physician in a multigroup practice participated in the study. This led to an imbalance of patients between the two groups and differences in patient demographics between the groups (Table 2). The data were reanalyzed using a mixed model to account for the imbalance, with no change in the findings.

The fact that patients in both groups lowered their BP to a similar degree during the study highlights the impact of focusing attention on hypertension. It can be better controlled with additional attention such as that which occurs when BP readings must be measured and recorded and BP adjusted by algorithm (12). It may be that if patients measure their own BP at home, it affects how their physician responds to their BP readings. For instance, in a research setting, if a doctor or study nurse knows that a subject is taking BP readings at home, perhaps he or she will treat the subject differently than if only office readings were being taken.

CONCLUSIONS

Participating in an intervention that highlighted patients with uncontrolled BP led to better control in both the treatment and usual care groups. Further research may determine the minimum intervention required in achieving BP control. On a wider scope, with the idea of patients being able to measure their own BP at home gradually becoming more plausible, further study may find that patients can reliably titrate their own medications at home.

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