



Clinical Research

The Gap Between Manual and Automated Office Blood Pressure Measurements Results at a Hypertension Clinic

Félix Rinfret,^{a,b} Lyne Cloutier, RN, PhD,^c Hélène L'Archevêque, RN,^b Martine Gauthier, RN,^b Mikhael Laskine, MD, MSc,^{b,d} Pierre Larochelle, MD,^b Monica Ilinca, MD,^b Leora Birnbaum, MD,^b Nathalie Ng Cheong, MD,^b Robert Wistaff, MD,^b Paul Van Nguyen, MD, PhD,^b Ghislaine Roederer, MD,^b Michel Bertrand, MD,^b and Maxime Lamarre-Cliche, MD, MSc^b

^aDépartement des sciences biomédicales, Université de Montréal, Montréal, Québec, Canada

^bInstitut de recherches cliniques de Montréal (IRCM), Montréal, Québec, Canada

^cDépartement des sciences infirmières, Université du Québec à Trois-Rivières (UQTR), Trois-Rivières, Québec, Canada

^dCentre de recherche, Centre hospitalier de l'Université de Montréal (CRCHUM), Montréal, Québec, Canada

ABSTRACT

Background: Blood pressure (BP) readings taken in clinics are often higher than BP readings taken in a research setting. Recent guidelines and clinical trials have highlighted the necessity of using automated office blood pressure (AOBP) devices and standardizing measurement procedures. The goal of the present study was to compare AOBP vs manual BP measurement in both research and clinical environments in which operators and devices were the same and measurement procedures were standardized and optimal.

Methods: Clinical manual BP and AOBP measurement estimates were gathered from a retrospective cohort of patients followed in a hypertension clinic. Research AOBP and manual BP measurement data were obtained from past research studies. Descriptive statistics and agreement analyses with Cohen kappa coefficients were developed. The AOBP/manual BP measurement gap between clinical and research follow-up was compared using an unpaired *t* test.

Results: Two hundred eighty-eight patients were included in the clinical cohort, and 195 patients contributed to research-grade BP

RÉSUMÉ

Introduction : Les mesures de pression artérielle (PA) prises en clinique sont souvent plus élevées que les mesures de la PA prises dans un cadre de recherche. Les dernières lignes directrices et les essais cliniques ont souligné la nécessité de procéder à la mesure de la PA en clinique - oscillométrique en série (MPAC-OS) et d'uniformiser les méthodes de mesure. Le but de la présente étude était de comparer les MPAC-OS et les mesures manuelles de la PA en milieu de recherche et en milieu clinique où les opérateurs et les appareils étaient les mêmes, et où les méthodes de mesure étaient uniformisées et optimales.

Méthodes : Les estimations des mesures manuelles de la PA et des MPAC-OS en milieu clinique provenaient d'une cohorte rétrospective de patients suivis dans une clinique d'hypertension. Les données des MPAC-OS et des mesures manuelles de la PA en milieu de recherche provenaient d'études de recherche antérieures. Les statistiques descriptives et les analyses de concordance à l'aide des coefficients kappa de Cohen ont été élaborées. Le test de *t* non apparié a comparé

Hypertension, a major cardiovascular risk factor, occurs in 22.6% of Canadians.¹ Its treatment has been shown to reduce stroke, ischemic heart disease,² and mortality.³ To address the disease adequately, clinicians must have reliable tools to estimate blood pressure (BP). Manual BP measurement by

sphygmomanometer has historically been considered the reference method to evaluate other types of BP measurement, but its validity depends on operator expertise and standard measurement procedures. Its use has been found to be associated with many biases,⁴ such as suboptimal adherence to measurement recommendations, preferential recording of 0 and 5 end digits, or inappropriate patient preparation and installation. Others, mainly the “white coat effect,” are inherent to operator presence.

In the past 10 years, there has been rising interest in automated office BP (AOBP) measurement. AOBP essentially refers to serial BP measurements taken by a device that

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Corresponding author: Dr Maxime Lamarre-Cliche, IRCM, 110 avenue des Pins Ouest, Montréal, Québec H2W 1R7, Canada. Tel.: +1-514-987-5550; fax: +1-514-987-5744.

E-mail: lamarm@ircm.qc.ca

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data. All patients had hypertension. AOBP averages were lower than manual measurement averages in both clinical (-3.6 ± 14.9 mm Hg / -3.0 ± 8.8 mm Hg) and research (-2.7 ± 10.0 / -2.4 ± 6.3 mm Hg) environments. The gap between measurement methods did not differ between research and clinical data. Cohen kappa coefficient was lower in the clinical context because of greater variability and more time between BP measurements (5.5 ± 2.9 months).

Conclusions: Manual BP readings were slightly higher than AOBP estimates. The difference was not influenced by the real-world context of clinical practice. Office nonautomated BP measurements may still be valuable if measurement procedures are well standardized and performed by trained nurses.

operates without human intervention between readings. AOBP has been shown to eliminate much of the white coat effect linked with office environments.^{5,6} Systolic blood pressure (SBP) measurement with AOBP has been determined to be about 10 mm Hg lower than that with standard manual office BP. Recently, the Cardiovascular Health Awareness Program study demonstrated that AOBP measurements predicted cardiovascular events.⁷ AOBP is recommended in Canada as the preferred in-office BP measurement method for hypertension diagnosis.⁸

In 2015, the **S**ystolic **B**lood **P**ressure **I**ntervention Trial (SPRINT) redefined targeted BP in a large subset of hypertensive patients according to AOBP measurements.⁹ Multi-national and Canadian guidelines have acknowledged the SPRINT results and have recommended lower BP goals with AOBP-based measurement protocols. Many clinics have had to modify their BP measurement procedures for application of these recommendations. At the IRCM hypertension clinic, BP was quantified manually by 1 of 2 specially trained nurses (H.L.A. or M.G.) on the basis of 2 previous studies showing that in a research environment, they obtained manual BP estimates equivalent to 24-hour ambulatory BP measurement and monitoring with a BpTRU device (1 study with unpublished results).¹⁰ In February 2016, BP measurement procedures were nonetheless reassessed, and AOBP was implemented as the mandatory BP measurement for all patient visits.

The general goal of the present study was to evaluate the performance of clinical AOBP measurements in an environment in which manual BP measurement was optimal. More specifically, the objective was to measure the gap between standardized manual BP and AOBP estimates and isolate the impact of the clinical environment on this gap. A change in the relationship from a research to a clinical perspective with otherwise the same factors would strongly suggest that even well-standardized BP measurement skills cannot compensate for the advantages of AOBP in real-world situations.

l'écart des MPAC-OS et des mesures manuelles de la PA entre le suivi en milieu clinique et le suivi en milieu de recherche.

Résultats : Parmi les 288 patients qui faisaient partie de la cohorte clinique, 195 patients ont contribué aux données de la PA de qualité recherche. Tous les patients faisaient de l'hypertension. Les moyennes des MPAC-OS étaient plus basses que les moyennes des mesures manuelles en milieu clinique ($3,6 \pm 14,9$ mm Hg / $3,0 \pm 8,8$ mm Hg) et en milieu de recherche ($2,7 \pm 10,0$ / $2,4 \pm 6,3$ mm Hg). L'écart entre les méthodes de mesure ne différait pas entre les données de recherche et les données cliniques. Le coefficient kappa de Cohen était plus petit dans le contexte clinique en raison de la plus grande variabilité et de la longue période entre les mesures de la PA ($5,5 \pm 2,9$ mois).

Conclusions : Les mesures manuelles de la PA étaient légèrement plus élevées que les estimations de la MPAC-OS. La différence n'était pas influencée par le contexte réel de la pratique clinique. Les mesures non automatisées de la PA au bureau peuvent encore être valables si les méthodes de mesure sont bien uniformisées et réalisées par des infirmières et infirmiers entraînés.

Methods

This chart-based retrospective cohort study assessed the gap between manual BP and AOBP measurements and compared the data obtained in research and clinical environments. It was performed at the IRCM hypertension clinic after approval by the local research ethics committee. Clinical BP estimates were taken from the hypertension clinic's patient files.

Inclusion criteria for the selection of clinic patients/charts were the following: (1) past regular follow-up at the hypertension clinic, with at least 1 visit before and after February 2016, (2) clinical manual BP recording by 1 of 2 specially trained nurses (H.L.A. and M.G.) before February 2016, and (3) clinical AOBP recording after February 2016. Patients with a change in hypertension treatment between the last medical visit before February 2016 and the first medical visit after February 2016 were excluded.

Manual BP data were collected during visits before the implementation of mandatory AOBP measurements in February 2016. AOBP data were obtained during visits after February 2016. For research environment data, study files from 2 past studies were reviewed (1 study with unpublished results).¹⁰ These investigations were selected because they assessed manual BP and AOBP measurements in hypertensive patients, and all data were collected by the same 2 hypertension clinic nurses. When participants were included in both studies (6 patients), only data from the most recent study were retained. Patient charts and study files were reviewed to extract clinical manual BP and AOBP data.

For research data, 3 manual BP measurements were recorded, but only the first measurement was used to allow better comparison with single BP measurements in the clinical environment. Sociodemographic data, body mass index, and arm circumference were also collected. Information on length of follow-up, antihypertensive drug use, and number of past visits was collected from clinical patient charts.

All manual BP measurements were recorded with mercury sphygmomanometers. All clinical and research AOBP

measurements were obtained with BpTRU monitors (model BPM-100, VSM MedTech Ltd, Vancouver, BC). All BP measurements were recorded according to Canadian Hypertension Education Program guidelines.⁸ Briefly, patients were seated in a chair with back support, legs uncrossed and touching the floor, with the arm resting at heart level. They were instructed not to eat or drink anything other than water or to smoke 30 minutes before their BP measurement. For manual BP assessment, patients remained seated for 5 minutes in a quiet well-lit room before measurement. All clinical and research manual BP measurements were recorded by the same specially trained nurses (H.L.A. and M.G.). The BpTRU monitor was operated by the same nurses and was set for 1-minute intervals between measurements. The operator left the patient alone during the entire cycle. The first reading was automatically discarded, and the 5 subsequent measurements were averaged by the monitoring device.

Clinical and research manual BP and AOBP estimates were first analyzed descriptively. The main outcome was the gap in SBP between manual BP and AOBP values. The data were assessed for normal distribution and presented with means and standard deviation (SD). Diagnostic agreement analyses were performed with contingency tables, and Cohen kappa coefficients were calculated. The control threshold in nondiabetic patients was defined as being < 140/90 mm Hg for manual BP measurement and < 135/85 mm Hg for AOBP measurement. The BP control threshold in patients with diabetes was defined as being < 130/80 mm Hg for both manual BP and AOBP measurements.

Before and after BP measurements were compared by paired *t* test. Clinical and research BP estimates were compared using an unpaired *t* test after patient files representing both research and clinical data were discarded (23 patient files).

The main hypothesis was that the gap between manual BP and AOBP measurements is different in clinical and research environments. At least 142 patient files per group needed to be included (α of 0.05 and β of 0.20) to demonstrate a clinically significant 5 mm Hg difference, with a 15 mm Hg SD. Additional patient files were added for data exclusion and subanalyses. Prespecified subanalyses assessed interactions between BP estimates and age, number of visits before study, and cuff size.

Results

In total, 288 clinical patient files and 195 research patient files were reviewed. Patient characteristics are enumerated in Table 1. Mean follow-up time of clinical patients before the study was 14.8 ± 11.2 years. The average time lapse between manual BP and AOBP measurements was 5.5 ± 2.9 months.

Table 2 reports average AOBP and manual BP estimates and gaps obtained in the clinical environment. No interaction was found between the BP results and age, past number of visits, and cuff size. Table 2 also presents average BP estimates and gaps encountered in the research environment. There were no significant differences in the AOBP/manual BP gap between the data from clinical and research settings. Figure 1 depicts SBP Bland-Altman graphs of the research and clinical data. For clinical SBP, 2 SD from mean BP values ranged

Table 1. Baseline characteristics of participants

	Clinical	Research
No. of patients	288	195
Age (y)	66.6 \pm 12.6	63.2 \pm 12.8
Male sex	147 (51%)	102 (52%)
Body mass index	28.7 \pm 5.8	28.6 \pm 6.11
No. of patients with cuff size:		
Small	9 (3.1%)	7 (3.6%)
Regular	202 (70.1%)	144 (73.8%)
Large	74 (25.7%)	39 (20.0%)
Extra large	0	5 (2.6%)
Number of antihypertensive drugs	2.3 \pm 1.2	1.8 \pm 1.3
Smokers (%)	21 (7.3)	30 (15.4)
Diabetes (%)	55 (19.1)	27 (13.8)

Estimates are mean and SD unless specified otherwise.

between -33.2 and 26.0 mm Hg. For research SBP, 2 SD from the mean ranged between -23.4 and 16.9 mm Hg.

Table 3 provides diagnostic performance comparisons of manual BP vs AOBP measurements in clinical and research environments. In the clinical environment, diagnostic agreement occurred 74% of the time, with a Cohen kappa coefficient of 0.472 (standard error [SE] \pm 0.052). In the research environment, agreement was 83%, with a Cohen kappa coefficient of 0.651 (SE \pm 0.054).

Discussion

The present study shows that when BP is measured manually according to all recommended standards, the resulting BP estimates are only slightly higher than those obtained with AOBP, and the difference between them is not influenced by comparison of the research and clinical environments.

A significant number of trials have compared manual oscillometric or auscultatory BP and AOBP measurements directly or indirectly with ambulatory blood pressure measurement (ABPM).^{5,6,10-21} In contrast to our study, they have disclosed that clinical manual BP measurements are greater than manual research BP estimates, which, in turn, exceed AOBP and ABPM measurements. They have also largely demonstrated that manual SBP measurements are greater than AOBP estimates by about 10 mm Hg. In these studies, environment, operator, and device differences were aggregated when comparing clinical manual BP and research manual or AOBP measurements. It may therefore be difficult to isolate the contribution of each factor to the resulting gap between clinical manual BP and research BP measurements. Another important factor to be considered is the identity of the operator measuring BP. A study led by Mancia et al.²² found that manual BP estimates taken by a physician were approximately 10 mm Hg higher than BP estimates taken by a nurse. These findings are consistent with a recent meta-analysis from Clark et al.,²³ which found a difference of 7 mm Hg between BP estimates taken by nurses and physicians. Several studies directly and indirectly comparing manual BP estimates and AOBP estimates used the referral physician BP estimate.^{5,6,12,14-16} In these studies, the fact that the physician took the BP measurement could explain the observed 10 mm Hg difference.

In the present study, operators and devices were the same for all clinical and research measurements, and adherence to

Table 2. Blood pressure data

Clinical environment, mm Hg	
AOBP	129.5 ± 17.2/74.3 ± 10.8
Manual	133.1 ± 14.9/77.3 ± 10.2
AOBP - manual*	-3.6 ± 14.8*/-3.0 ± 8.8*
Research environment, mm Hg	
AOBP	132.6 ± 19.4/75.8 ± 11.0
Manual	135.3 ± 19.5/78.2 ± 11.4
AOBP - manual	-2.7 ± 10.0*/-2.4 ± 6.3*

Estimates are mean and SD unless specified otherwise.

AOBP, automated office blood pressure.

* $P < 0.001$ (paired t test).

standardized procedures was optimal for all measurements. The results consequently reflect more adequately the impact of environment on the gap between manual BP and AOBP estimates. It can be suggested that the observed gap of < 4 mm Hg between manual and AOBP measurements and the apparent lack of an impact from the clinical environment indicate that adherence to measurement recommendations has a major impact on manual BP estimates. The small residual gap results from the nature of the AOBP multiple measurement strategy and operator absence during measurement. This study also demonstrates that standardized and reliable BP procedures can be implemented in clinical environments.

Manual BP measurements were recorded with mercury devices, but aneroid or oscillometric devices are more common in the clinic. The latter 2 devices could have been used and would have resulted in similar BP estimates. The choice of mercury devices should not be detrimental to the conclusions drawn from this study. In some respects, these well-calibrated instruments add validity to manual measurements. Similar to other devices, they are sensitive to any operator-related biases that could impact BP estimates.

Variability in the gap between manual BP and AOBP measurements was greater in the clinical environment than in the research environment in the present study. This observation is evident from the Bland-Altman graphs. It can also be seen in agreement analyses, demonstrating lower Cohen kappa coefficients in the clinical environment. This could be the result of the more stressful nature of real-world clinical situations and the impact of measurement procedures as well as patient hemodynamics. The authors of the current study

Table 3. Achievement of therapeutic goals determined by BP measurement type

	AOBP		Total
	Yes	No	
Clinical context*			
Manual BP			
Yes	124	34	158
No	41	89	130
Total	165	123	288
Research context†			
Manual BP			
Yes	84	20	104
No	14	77	91
Total	98	97	195

AOBP, automated office blood pressure; BP, blood pressure.

* 73.9% of agreement; kappa = 0.472 (SE = 0.052).

† 82.6% of agreement; kappa = 0.651 (SE = 0.054).

believe, though, that it is because of the much greater time difference between manual BP and AOBP measurements in the clinical environment. This difference was inherent to the contrast in experimental methodology for clinical and research cohorts. Research BP measurements were obtained prospectively and in a limited time frame, because they were planned beforehand and recorded optimally. The clinical data, in contrast, were obtained retrospectively and were observational in nature and inherent to real-world environments. This methodology is advantageous because the nurses quantifying BP were not aware that their measurements would be analyzed, obviating the possibility of a Hawthorne effect. Consequently, the clinical BP observations adequately reflect real-world clinical environments. Clinical measurements were always recorded in the same manual-first and AOBP-second sequence, as reported in the Methods section. Regression to the mean could have influenced the results, but this was probably not the case because the great majority of participants were long-time patients, and no statistical interaction was observed between the length of follow-up before the first visit and the BP results.

Hypertension guidelines underline the importance of AOBP measurement strategies to help in hypertension diagnosis and treatment. Many have introduced AOBP measurements in their clinical practice, but others have not been able

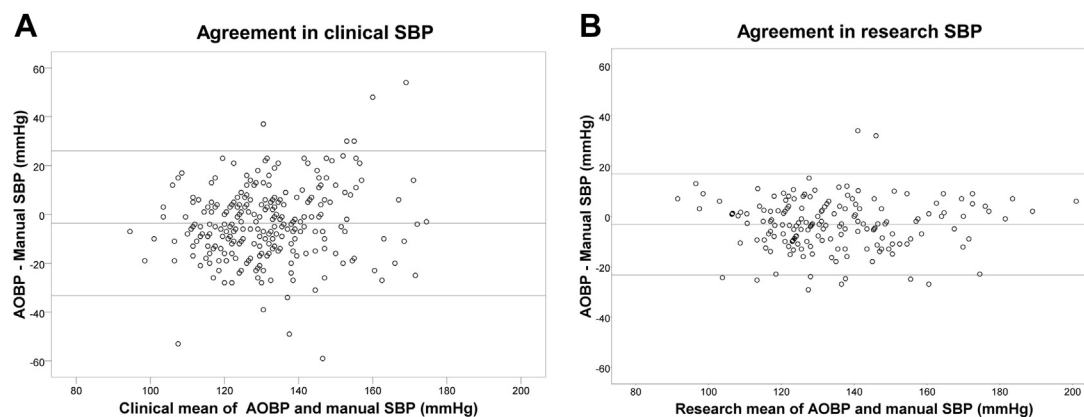


Figure 1. Bland-Altman plots of SBP in (A) clinical and (B) research settings. AOBP, automated office blood pressure; SBP, systolic blood pressure.

to do so. The acquisition of AOBP devices and, mostly, the identification of isolated space for BP measurement can be challenging. The results of this study should not be interpreted such that manual BP is equated with AOBP measurement. The latter is much less prone to operator-derived biases and has been shown to reduce the white coat effect. Nonetheless, there are many types of BP measurement devices still in use and some questions about the way they relate to AOBP. Should casual unstandardized SBP results be interpreted as AOBP plus 10 mm Hg? Data from this study suggest that well-standardized manual BP measurements obtained by nurses are higher than AOBP estimates by < 5 mm Hg on average, even in a clinical setting. It should be emphasized that the results of our study may not apply to a majority of clinical settings, because for practical reasons BP measurement procedures are not optimal. Previous studies showed that the clinical difference between AOBP and manual measurements are greater when the quality of the BP measurement is not standardized.^{5,6,12,14-16}

In conclusion, the present work emphasizes that nonautomated BP measurements can still be a valuable diagnostic tool that is generalizable from a research to a clinical perspective. As long as they are well standardized and performed by well-trained nurses, our study suggests that manual BP estimates should stay within a 5 mm Hg margin of AOBP measurements.

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Disclosures

The authors have no conflicts of interest to disclose.

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