Title: Blood Pressure Measurement: Should Technique Define Targets?

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Lay Summary

Hypertension is the single most important risk factor for cardiovascular disease and death. Over the last several decades many classes of blood pressure lowering drugs have been discovered. These allow physicians to achieve optimal blood pressure and prevent adverse cardiovascular outcomes in most patients. However, the optimal blood pressure level has changed over time, and most recently has been decreased to 120 mm Hg, on the basis of clinical trials. These trials used a specific rigorous method of blood pressure measurement (patient alone in room, enforced period of rest, average of multiple readings) that is currently not the standard of practice in most clinics. Blood pressure itself is highly influenced by technique and device. In particular the length of resting time (if any), and whether it is measured with device requiring medical personnel presence in the room or not. For the same individual, the difference between blood pressure taken with and without rest could be 10 mmHg, and presence vs absence of medical personnel in the room during rest and/or BP assessment could be another 10 mmHg. Hence, the target blood pressure could vary materially based on BP technique and device used. As it is unlikely that all physicians can change their practice overnight and embrace blood pressure device allowing for standard resting time and unattended blood assessment, a comparative pragmatic study of the blood pressure technique and devices endorsed by Hypertension Canada and used in Canada is desirable to avoid either over- or under-treatment of Canadian patients with hypertension. In the present study, we will compare 4 different methods of measuring blood pressure in the office (casual, resting average of 3 readings with nurse present of absent for resting period, and average of 5 readings) as well as a 24 hour ambulatory measurement in 90 patients.

The results of this study will help and enable practicing family physicians and specialists in Canada to target BP for their patients based on algorithm and method of assessment of BP they use in their offices.

Background

Hypertension prevalence

Hypertension is a chronic disease with a tremendous burden. Its prevalence is estimated globally at about 20%, with an increasing trend continuing in the last 15 years(1). Hypertension is highly prevalent among adult Canadians (at about 26%). The prevalence of hypertension increases from about 4% in young adults (< 30 years of age) to more than 50% among those 60 years of age and older. Altogether, hypertension is extremely relevant vascular disease among adult Canadians.

Hypertension and Clinical Outcomes

Hypertension is the single most important risk for adverse vascular outcomes, comprising stroke, heart disease, and both cardiovascular and all-cause mortality. The estimated annual death rate per 100 000 associated with systolic BP of 140 mm Hg or higher is about 106(1). The largest numbers of hypertension related deaths were caused by ischemic heart disease (4.9 million; 54.5%), hemorrhagic stroke (2.0 million; 58.3%), and ischemic stroke (1.5 million; 50.0%)(1). Loss of disability-adjusted life-years (DALYs) associated with systolic BP of 140 mm Hg or higher are estimated to be about 143.0 million US dollars(1). Treatment of hypertension, using randomized controlled trials (RCTs), showing repeatedly that the risk of these adverse vascular outcomes is decreased by sustained blood pressure (BP) lowering.

Advances in Pharmacological Treatment of Hypertension

Back in 1940, patients diagnosed with hypertension had very limited treatment options: either an extreme low salt diet and/or dorsal lumbar sympathectomy, both very radical measures, reserved for individuals with malignant hypertension, at what we would now consider extremely high blood pressure levels (with target organ damage). Over the last 75 years, more than 7 different classes of BP lowering drugs have been discovered. Hence in the modern era, almost all patients with hypertension can have BP level decreased to desired numbers. Hence the research focus has moved from *how* blood pressure *could* be decreased, to *how much* blood pressure *should* be decreased, and in *whom* should these targets apply.

Blood Pressure Treatment Targets

Targets for BP have been largely established based on results from prospective observational studies, which show a progressive rise in adverse cardiovascular outcomes from the levels of systolic BP above 120 mmHg with a steep rise with systolic BP above 140 mmHg. RCTs confirmed these findings and showed that decreasing BP below 140 mmHg in the general populations, 150 mmHg in the very elderly patients, and 130 mmHg in patients with diabetes mellitus significantly reduces adverse vascular outcomes such as stroke, chronic heart failure, myocardial infarction, and mortality. Recently, new trials tested the hypothesis of whether patients with the highest cardiovascular risk benefit from even lower targets of systolic BP(2).

The Systolic Blood Pressure Intervention Trial (SPRINT) and its relevance for BP target in patients with high cardiovascular risk

In this prospective, randomized controlled trial funded by NIH, patients with high cardiovascular risk (Framingham Cardiovascular Risk Score > 15%, average 21%) were randomized to standard treatment targeting systolic BP < 140 mmHg or to intensive BP lowering regimen targeting systolic BP < 120 mmHg(2). This trial, with 9,361 patients, was stopped early after an average follow up period of 3.2 years after patients randomized to the intensive BP lowering arm experienced a clinically significant decrease in primary outcome (comprising of stroke, acute coronary syndrome, congestive heart failure, and cardiovascular death). Following this development, a new target of systolic BP < 120 mm Hg for patients with hypertension and high cardiovascular risk has been recommended by major national professional organizations including Hypertension Canada/Canadian Hypertension Education Program, in their most recent Guidelines on the Diagnosis and Treatment of Hypertension(3). However, in the discussion around the benefits and risks of more intensive BP lowering, insufficient attention has been focused on the method of BP measurement in SPRINT, and how it compares to existing methods(4).

Which BP reading is the most relevant to predict adverse vascular outcomes?

Over the years it became clear that a single office BP reading provides only a snapshot of the overall BP load. As expected, repeated office measurements of BP provide better assessment of BP load and overall adverse hypertension related vascular outcomes. 24 hour ambulatory BP monitoring (ABPM) provides the ultimate assessment of overall BP load during the daytime and nighttime. ABPM allows for identification of white coat effect (out of office BP is lower than office BP) and masked effect (out of office BP is higher than office BP). Measurement of the diurnal variation also allows for identification of nocturnal blood pressure. The average nighttime BP appears to be the single most important predictor of adverse vascular outcomes, followed by average daytime BP, and repeated office BP recordings. ABPM is, however, not an insured service covered by the provincial health insurance in Ontario, or the rest of Canada. Finally, home BP measurements, in combination with repeated office BP readings, have also become more commonly used now. But home BP is not used by all patients, there is an additional cost involved, and home BP monitors may not be accurate. In the real world, hence, office BP readings remain the most commonly method used for diagnosis and the management of hypertension. Hence it is crucial that accurate methods are used for office BP measurements.

Automated oscillometric BP devices replaced mercury sphygmomanometry

Mercury sphygmomanometry was, for nearly 100 years, the most commonly used technique for office BP assessment. However, readings using this technique are not as accurate and reproducible as one may have thought. Firstly, accuracy is highly dependent on the skills of

health care professional, and is not only susceptible to human error and listening skills, but also to terminal digit preference (rounding to '0'). Secondly, at least 20% of patients display higher BP readings with health personnel in the room than in real life (white coat phenomenon). Additionally, about 10 - 20% of patients have lower BP readings in the office than in real life (masked hypertension). Automated oscillometric BP devices (AOBP) eliminate the human error as well as attenuate the white coat effect, since they allow for multiple readings to be taken in (un)attended fashion. Observational studies have reported that BP measurements with AOBP devices are predictive of cardiovascular events. Because of these two major advantages, Hypertension Canada recommends automated oscillometric devices as the method of choice for office BP measurement. In the last decade, AOBP devices, which typically provide an average of 3-5 measurements, have become widespread for use in specialist clinics, and, especially, in general practice. Several features of automated measurements are noteworthy and relevant for further discussion.

Relevance of human error and presence of medical personnel for BP readings

Even trained medical personnel are prone to round up or down actual BP readings to the closest zero (5, 6). Automated oscillometric BP devices eliminate this error(7, 8). In addition, they mitigate a risk for human error related to variable training, and hearing deficit (6-8). Furthermore, the presence of medical personnel during BP readings imposes a positive bias on BP, the 'white coat effect'. This effect may differ from person to person, likely related to varying susceptibility for white coat effect between patients (4, 9). By contrast, automated oscillometric devices allow for BP assessment in an unattended fashion. Not surprisingly, the differences between office BP readings taken by automated oscillometric devices and mercury sphygmomanometers can be relatively large. For example, Myers et al reported a positive bias for BP readings taken by manual measurement of 13.9 mm Hg, compared to the automated oscillometric device(10). Other studies, including those by our group, concur with this important degree of positive bias imposed by human error and presence of medical personnel in the room during BP readings (11, 12). Finally, casual BP readings taken immediately after patient arrival to the office, without prior resting, are also materially higher compared to those taken after a rest period. In the recent study by Agarwal, systolic BP readings by using the technique and the same device employed in SPRINT were 12.7 mmHg lower as compared to single office non-resting office BP reading taken by another oscillometric device, in the presence of a medical personnel (13). Indeed, the presence of another person who is talking has been reported to result in a positive bias ranging from 4 – 19 mm Hg in systolic BP (6). In addition, just the presence of a health personnel (who is not talking) as well as the hospital environment itself are the major component of the white coat effect (14). The automated devices attenuate this effect by virtue of allowing (a) unattended BP measurement and (b) taking an average of multiple readings.

	Method	Device	Details	Comments	Difference	BP trend
1	Casual blood pressure	Oscillometric device, rarely mercury	First BP measured as patients walks into the clinic	Can be artificially high (white coat effect)	*Reference*	Higher
	Resting Blood pressure methods					
2	BPTru	BPTru device	No extra period of rest 1st reading by Nurse, who leaves room 5 additional readings 1-2 minutes apart, output = average of 5	Reduces white coat effect Associated with CV outcomes. Commonest method used in Canada	~ 5-8 mm Hg lower	
3	Omron HEM 907XL, partly attended	OMRON HEM 907XL	5 minutes of unattended rest, Nurse enters room 3 BP readings, output = average	Method used in SPRINT	~ 12 – 13 mm Hg lower	
4	Omron HEM 907XL, unattended	OMRON HEM 907XL	5 minutes of unattended rest, 3 BP readings, output = average *Patient alone in room throughout*		Not known, ? 15 mm Hg	Lower
	Ambulatory Blood pressure					
5	ABPM	Many devices, eg Spacelabs	Oscillometric device; left on for 24 hours. Records every 30 minutes while awake, 60 minutes when asleep	Linked to CV outcomes; diagnosis of white coat and masked effect; shows diurnal variation in BP	~ 5 mm Hg lower	

Resting time and Blood Pressure levels

Ideally, BP measurement should be done after a 5 minute period of rest, as per recommendations and best practices. Indeed, insufficient rest period can result in a positive bias ranging from + 4.2 to + 11.6 mm Hg(6). Unfortunately, in the real world setting, proper resting is rare, and results 'routine' BP measurement were reported to be higher by 5.3 mm Hg compared to properly done resting BP(15). Importantly, the longer the rest, it appears, the lower the BP readings, even beyond the normally recommended 5 minutes. In this regards, Nikolic et al compared BP readings taken by automated oscillometric BP device after 5 and 10 minutes of rest (16). Readings after an additional 5 minutes of rest were lower -4.2 mm Hg. This study indicates that the number of minutes of rest prior to BP readings could indeed have a clinically meaningful impact on the result, above and beyond the 'normal' resting period of 5 minutes. Until recently, it was left up to medical personnel to assure that BP readings were taken after 5 minutes of rest. While there are no studies on quality assurance in this regard, it seems reasonable to assume that readings taken by medical personnel are taken with widely varying degrees of rest, thereby seriously undermining the clinical interpretation of the result(15). The Omron HEM 907 XL, used in SPRINT, is the first automated oscillometric BP device that allows for a pre-set defined resting period of 5 minutes, in accordance with guidelines on BP measurement by national professional organizations. This device thus allows for the removal of the other element of human error, an inadequate resting period. Additionally, based on the results of SPRINT, this device does have strong data in terms of its use for BP measurement and management and reduction in clinical outcomes. However, this device and method is not yet in widespread use in clinical practice.

Barriers to Implementation of BP methods from SPRINT into routine clinical practice

An enforced 5 minutes of rest and 3 BP readings taken about 1 minute apart (with about 20 seconds per reading) results in an additional 9 minutes of time. Incorporating this method of BP measurement will result in a significant increase in time spent for a routine clinic visit both for the patient and for the provider office. The logistics involved may thus require not just the additional cost of purchasing new devices, but also additional space, such as a separate room to allow for patient flow. These barriers are still very important to surmount, given the fact that using this method results in more accurate data, and can result in improved outcomes. Given that the BPTru automated devices (which provide no pre-set rest, average of 5 readings) are already in widespread use, data on the comparability of these two methods would thus be very useful. However, comparative data on automated oscillometric devices with and without pre-set resting period preceding BP assessment, are however lacking at this time.

Translational knowledge gap

The above data clearly indicate, that there is a significant gap after the SPRINT and that is whether and to what extent office BP technique determines the target for systolic BP. Use of currently practiced methods (eg casual BP, automated BP with BPTru) for BP measurement, while using targets derived from SPRINT may result in undertreatment or overtreatment of hypertensive patients, putting them at risk for cardiovascular outcomes, or exposing them to risk of unnecessary adverse events, respectively. As we outlined in our review, taking into account the lack of comparative data on differences between BP methods and devices used in clinical practice and their effect on BP, comparative studies of casual, attended vs non-attended BP readings with and without rest, and daytime BP averages from 24-hour ambulatory BP monitoring devices will be important to guide individualized hypertension care (see Appendix, "Precision medicine for hypertension management in chronic kidney disease: Relevance of SPRINT for therapeutic targets in non-diabetic renal disease" Ruzicka M., et al Can J Cardiol, 2017, in press). This is exactly the knowledge gap which this study aims to address.

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Project Design, Methodology and Analysis

In this study, we propose to compare the two commonly used automated oscillometric BP devices (ie BPTru, most commonly used in Canada and OMRON HEM 907XL, used in SPRINT) as well as ambulatory blood pressure monitoring (ABPM) with the most commonly used 'casual' blood pressure (BP) (see table below for details about the different BP methods). In addition, the measurements with the Omron HEM 907XL will be conducted in two different ways, with the nurse present after the quiet resting period, but during the BP measurement (ie partially attended), or the patient being completely alone (unattended). This will allow us to determine the effects of extra time, the difference between devices and being partially attended or completely unattended.

Study Design

We propose to perform a prospective, randomized, cross-over study to compare two different blood pressure (BP) BP measurement methods (see figure 1 for study flow).

Study Population

This is a low risk trial where the only `intervention' is additional BP measurements, and office visits for the same.

Inclusion criteria

All patients being followed in the Renal Hypertension Clinic will be eligible for enrolment.

Exclusion criteria

These will be focused on those patients for whom oscillometric measurements may be difficult

(1) inability to do oscillometric measurements (eg arrhythmias, pain, device reporting error)

(2) inability to consent the patient

Study Procedures

Eligible patients will be randomized to three groups, to have BP assessed on 2 different visits as follows (also see figure 1). All patients will have casual BP taken at baseline.

Group 1:

Visit # 1: Patients will have oscillometric device, BpTru (method 2 from table) applied to the arm with the higher BP. This will allow assessment with the commonest used Canadian device, which provides an average after 5 unattended readings. This assessment will be followed by 24-hour ABPM.

Visit# 2: Upon returning 24-hr ABPM device, the patient will have the Omron HEM 907XL applied to same arm as BPTru above. There will be 5 minutes of quiet rest (patient alone) and 3 readings subsequently (patient still alone) with the average being noted (method 4 from table). This measurement will be compared to casual BP for primary outcome.

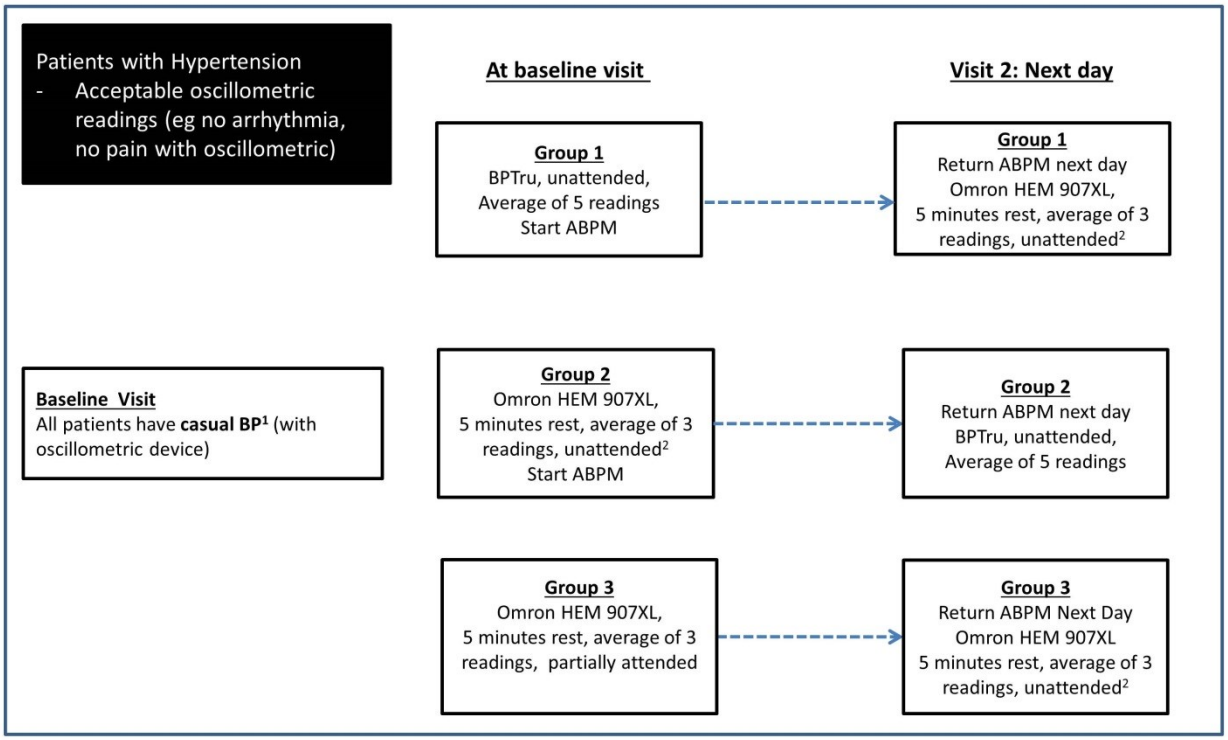
Group 2

They will undergo same process as group 1, in the reverse order (see figure 1, below).

Group 3

Visit # 1: Patients will have the Omron HEM 907 XL applied to the arm with the higher BP. There will be 5 minutes of quiet rest (patient alone) and 3 readings subsequently, *but with the nurse entering the room* (ie partially attended), with the average being noted (method 3 from table). This was the method most likely to have been used in SPRINT(1). This assessment will be followed by 24-hour ABPM.

Visit# 2: Upon returning 24-hr ABPM device, patient will have the Omron HEM 907XL applied to same arm as before. There will be 5 minutes of quiet rest (patient alone) and 3 readings subsequently (patient still alone) with the average being noted (method 4 from table).



Primary Outcome:
Difference in systolic BP between Casual BP[1] and Omron HEM 907XL, unattended[2]

Outcome Measures

Primary outcome measure

The effect of unattended 5-minute rest preceding unattended systolic BP assessment will be derived from the difference between casual BP and average resting unattended SBP pressure measured with the Omron HEM 907XL (ie methods 1 and 4 in table 1).

We will also report three **secondary outcome measures**

1/ difference between average SBP measured with BPTru and Omron HEM907 XL (methods 2 and 4 in table 1) will allow us to report the effect of the additional 5 minutes of rest,

2/difference between SBP at 10 minutes between the two visits in Group 3 (ie methods 3 and 4 in table 1) will address an issue of unattended versus partially attended resting SBP,

3/we will report the difference between the average unattended SBP and daytime average BP from 24-hr ABPM (ie methods 4 and 5 in table 1).

Analytic Plan

We will report descriptive statistics for variables of interest. We will report continuous variables as mean and standard deviation and categorical variables as proportions. For the outcome comparisons, we will use the student's t-test. See details for sample size estimation below. However, the mean differences are measures of average *bias* and not accuracy, or

precision. For the latter, plotting the difference between methods against the mean of the two methods, as suggested by Bland and Altman, are necessary(2). Hence, Bland-Altman scatter plots will be used to display the BP measurement data with the various methods, and we will also report the 95% limits of agreement as suggested by Bland and Altman. Lastly, we will carry out exploratory analysis to assess the effect of certain key covariates (eg age, sex, diabetes, presence of white coat or masked effect) on the mean bias between effects.

Rationale for the proposed sample size and power

The magnitude of the difference between casual and unattended average of 3 oscillometric readings after 5 minutes rest appears to be about 12.7 mmHg (3). Our review of the literature identified a range of possible standard deviations from 5 to 16 mm Hg. To be conservative, we will assume a standard deviation of 16 mm Hg. Hence, a sample size of 55 will give 90% power with a t-test at an alpha of 0.05. We anticipate little loss to follow up given the short nature of the study (2 visits 1 day apart). In addition, we will enrol an additional 30 patients in whom we will compare the effect of partially attended versus completely unattended blood pressures. We assume that a maximum of 5 patients may have errors with BP measurements with oscillometric methods. Hence we will plan to enrol 90 patients in this trial.

Team, Expertise and Resources

This study will be managed by the Kidney Research Centre in Ottawa, which has dedicated administrative staff and experienced clinical research coordinators, and conducts several clinical trials. Hypertension Specialists/Nephrologists, Drs. Marcel Ruzicka, Cedric Edwards, Swapnil Hiremath will oversee patient recruitment, and all described investigations, and will be responsible for collection and evaluation of all data. A dedicated and experienced staff nurse at Renal Hypertension clinic will perform all BP assessments. The nurses at this clinic are all certified RN, with additional certification in nephrology (C Neph), with additional experience in BP measurement. The data analysis will be conducted by Swapnil Hiremath, nephrologist and epidemiologist and Tim Ramsay, senior biostatistician and director of the Methods centre in Ottawa.

Timelines and Deliverable

Upon successful application for funding of this proposal, a clinical research coordinator within the Kidney Research Centre will be identified, and requisite devices purchased. We assume completion of recruitment 6 months as about 100 patients with hypertension are seen every week in the hypertension clinic every week, and the inclusion criteria for this study are very broad, with only 2 extra visits, above the standard of care. See table below for anticipated timeline of completion of project.

	Startup, Obtain devices, REB approval	Recruitment	Complete follow up	Data analysis, Interpretation, preparation of manuscript
0-3 months				
3-9 months				
9 - 12 months				

Anticipated results and Interpretation

We anticipate three possible results with this study. It is possible that the results show a tight, precise, bias between casual and unattended OMRON HEM 907 XL readings (primary outcome). This bias would then allow for calibration of results such that it would be possible to have different targets based on method of BP measurement. It is also somewhat possible, that though we might find an average bias that is significant, that this may not be precise, ie with a lot of scatter seen in the Bland Altman plot. In this case, it would be useful to examine if there are reasons for higher or lower bias (ie association of covariates with the bias) to allow for adjustment/calibration based on the population. Indeed, it may be that there are no such factors, in which case, the outcome could be that casual BP measurements should be abandoned completely, especially if considering intensive BP targets such as in SPRINT. The other additional BP measurements would also allow us to make similar inferences, apart from the scientific aspect of being able to tease out the effect of waiting additional time, and the presence of a nurse.

Knowledge Translation

The results of the study will be presented at national and international conferences (Canadian hypertension Congress, and American Heart Association – Council for High Blood Pressure). In addition, publication of full results will be done in a peer reviewed journal. We will also use social media, such as Twitter and Youtube, for dissemination of the results to a wider audience. In collaboration with the Office for CME of the University of Ottawa, Drs. Edwards will oversee development and delivery of teaching modules on BP targets for Canadian patients with hypertension using difference BP techniques for family physicians and other primary care providers. Drs. Marcel Ruzicka and Swapnil Hiremath are members of the Recommendations

Task Force (RTF) for the Hypertension Canada guidelines, and will present the results to the same for possible incorporation in the next iteration of the guidelines, as appropriate.

Potential Challenges and Mitigation

Recruitment

Recruitment is always a challenge for prospective studies. However, we work in a centre with a large catchment area, and the hypertension clinic receives ~ 200 new referrals every year, and about 1100 patients are being currently followed up in the clinic. Also, we perform 20-30 ABPM procedures every week. In addition, the inclusion/exclusion criteria are very broad, thus most patients will be eligible for participation in this study. Lastly, the design for an individual participant is rather simple, with no invasive procedures, and only two additional visits.

Loss to Follow up

The study has only a 24 hour follow up, when participants return the ABPM device, hence we anticipate very little loss to follow up.

Inadequate/errors in BP measurement

It is indeed true that oscillometric devices do not always capture the correct blood pressure. Hence as part of the exclusion criteria, we will exclude patients in whom this happens, irrespective of the reason (eg arrhythymia, pain etc). In addition, we have increased the sample size by 5 to account for additional error that may occur in the eligible patients.

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