Cluster-Randomized Controlled Trial of Oscillometric vs. Manual Sphygmomanometer for Blood Pressure Management in Primary Care (CRAB)

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BACKGROUND
Although mercury sphygmomanometers are seen as the gold standard instrument for blood pressure (BP) measurement, they are being withdrawn due to safety concerns. CRAB was a cluster-randomized controlled trial in 24 family practices in Tasmania, Australia, which aimed to determine the effect of an oscillometric device on BP management.

METHODS
Cluster-randomized controlled trial. Intervention practices were supplied with automated monitors and control (usual care) practices used mercury or aneroid sphygmomanometers. They were subsequently audited by a research nurse. Usual care practice audit periods were matched to intervention practices. All analyses were intention-to-treat and adjusted for potential clustering. Differences in BP were analyzed using generalized estimating equations. All other outcomes were analyzed using multilevel mixed-effects Poisson regression. Post hoc analyses were performed to determine the mediators of changes in prescribing behavior.

RESULTS
A total of 3,355 records were reviewed (828 visits had BP recordings). The percentage of BP recordings ending in "0" was significantly lower in intervention vs. usual care practices (systolic BP (SBP) 18% (107/587) vs. 71% (233/329), diastolic BP (DBP) 20% (119/584) vs. 70% (229/328), P < 0.001). The mean of SBP recordings in the intervention group was 7.5 mm Hg (95% confidence interval (CI) 5.2, 9.9 mm Hg, P < 0.001) higher than in the usual care group. Patients taking BP lowering drugs were more likely (incidence rate ratio (IRR) 1.3, 95% CI 1.1, 1.7, P = 0.01) to have a BP lowering drug prescribed if they were in the intervention compared to the usual care.

CONCLUSIONS
Although digit preference was largely eliminated by oscillometric measurement, prescribing behavior was mediated by SBP.

recorded and who have more than one BP measurement recorded; 
2. alter the number of new and existing antihypertensive BP medications prescribed to patients with previously diagnosed hypertension; 
3. increase the number of dose adjustments to antihypertensive medication in patients with previously diagnosed hypertension; 
4. decrease the mean recorded SBP and DBP.

**METHODS**

**Study procedures.** CRAB was a cluster-randomized trial of 24 family practices conducted January–March 2007. A cluster-randomized controlled study design was chosen because the intervention was unblinded and therefore at risk of contamination. Family practices were recruited by facsimile to all Hobart members of General Practice South, an organization supporting >300 FPs and 90 family practices in the south of Tasmania. Practices were excluded if they had existing oscillometric BP devices. Intervention practices were supplied with OMRON HEM-907 monitors (Omron Healthcare, Kyoto, Japan) for all clinical rooms and other BP measuring devices were temporarily removed (Figure 1). The machines were programmed to take three BP measurements 30 s apart and to average the last two measurements and provide a single final measure of SBP and DBP. FPs were given a one page summary of the use of the machine (and its study settings) and the manufacturer’s instruction manual. The OMRON HEM-907 device is a validated BP measurement device.9–11 Compared to simultaneous measurement with a mercury device via a Y tube Assaad et al. reported an average difference of $-1 \pm 7$ mm Hg and $-5 \pm 6$ mm Hg for SBP and DBP, respectively.10 Usual care practices delivered their usual care (usual care group) using manual sphygmomanometers and were supplied with automated devices at the end of the trial to prevent dropout.

Computer-generated random numbers were used to allocate practices using permuted block randomization in blocks of four. Practices were allocated by a researcher who was blinded to the identity of practices until after completion of data collection and who was not involved in recruitment or data collection. The randomization sequence was concealed from researchers involved in recruitment and data collection until the intervention was assigned.

Intervention practices had a 1 week run-in phase to familiarize themselves with the machines and to reduce their novelty. Intervention practices were subsequently audited for the second week with the machines in situ and a single day before supply of devices by a research nurse as prospective collection of data by the FP may have influenced the outcome measures of interest. Usual care practice audit periods were matched to intervention practices. The purpose of the preintervention audit day was to establish that BP recording and management before intervening did not differ between intervention and usual care groups.

All patient records of individuals aged $\geq 18$ years who attended the practice during the specified times, and were seen by a consented FP were audited. The records were audited per attendance for the study period for age, sex, any BP recording

**Figure 1** | Flow chart of CRAB. BP, blood pressure; FP, family physician; GP, general practice.
or not, all BP recordings, current antihypertensive medication, type and dose regimen, antihypertensive medication prescriptions written, and whether they were new or continuing, and antihypertensive drug dose adjustments.

All trial endpoints were measured at the individual patient attendance level. The primary trial endpoint was digit preference in BP recordings as measured by the proportion of BP measurements recorded which ended in “0”. Secondary endpoints were:

- number of BP readings recorded;
- number of prescriptions of antihypertensive medications;
- number of dose adjustments of antihypertensive medications;
- mean of SBP recordings;
- mean of DBP recordings.

Statistics. Statistical power was calculated assuming a level of significance set at 0.05 (two-tailed), an intracluster correlation of 0.013 conservatively based on the maximum of such correlation reported by Donner,12 10 family practices in each arm of 0.013 conservatively based on the maximum of such correlation reported by Donner,12 10 family practices in each arm (after allowing for four dropouts) with each practice seeing 90 eligible patients per day and ~5% of patient encounters being ineligible because they had repeated encounters in the same week, for a total of 4,275 eligible patient encounters in each arm. We assumed a baseline BP recording rate of 10% and a prevalence of hypertension of 8.8% (ref. 13).

For our primary hypothesis, the estimated 428 BP readings made in each arm gives power of 0.80 to detect a difference of 11% in the proportion of readings ending in zero between the usual care and intervention arms. For secondary hypotheses 1–3, we had power in excess of 0.70 to detect the differences in mean SBP and DBP were 3 and 2 mm Hg, respectively.

All statistical analyses were carried out on an intention-to-treat basis. BP readings were included in the analysis for the first visit only of each patient during the postintervention audit period, and where multiple readings were taken at that visit the mean BP reading for that patient was used. Differences in mean BP recordings between intervention and usual care groups were analyzed using generalized estimating equations. All other outcomes were analyzed using multilevel mixed-effects Poisson regression and expressed as incidence rate ratios (IRR) with 95% confidence intervals. The IRR measures the ratio of the event rate (i.e., terminal digit preference or prescribing behavior) in the intervention group divided by the event rate in the usual care group and is a consistent estimator of relative risk.14 All models were adjusted for the fixed effects of patient age and gender and, where possible, the random effects of practice and FP, with an independent covariance structure. If convergence was not possible, the models were adjusted for practice only. Routine diagnostics were performed on prescribing behaviors and potential mediators were added to successive models to identify those factors that determine prescribing behaviors. All analyses were carried out using Stata 10.0 (StataCorp, College Station, TX).

This study received approval from the Human Research Ethics Committee (Tasmania) Network (H9092) and registration on the Australian and New Zealand Clinical Trials Registry (Number 12607000083493). Informed consent was obtained from the participating physicians.

RESULTS

Twenty-four practices with 53 participating FPs were enrolled and 3,355 records (1,333 hypertensive individuals) were reviewed with 828 BP recordings (Figure 1). The

Figure 2 | Last digit of blood pressure recordings during prestudy day (usual care n = 106, intervention n = 105) and study week (usual care n = 308, intervention n = 460). DBP, diastolic blood pressure; SBP, systolic blood pressure.
The number of FP practices in our region. Sixty-five percent of FP practices worked in practices in which there were more than two FPs participating in the study. There were no statistically significant differences between the intervention and usual care groups for any of these FP characteristics. In the 1-day preintervention audit, there were no statistically significant differences between the intervention and usual care groups for any study outcome.

Last digit BP recording is shown in Figure 2. This shows that a strong preference for recording an end “0” preintervention and a markedly smaller proportion of end “0” recordings in the intervention arm postintervention. Oscillometric recordings approximated the expected 10% for each other digit ending whereas manual recordings still showed a secondary preference for “5”.

There were no significant differences between the intervention group and the usual care group in the proportion of patients in whom a BP reading was recorded (IRR 1.16, 95% CI 0.84, 1.60, P = 0.25), or between the proportion of patients in whom more than one BP reading was recorded (IRR 1.58, 95% CI 0.30, 8.3, P = 0.65) (Table 1). In those patients who were taking BP lowering medication, the proportion of patients who had a BP measurement taken, or had more than one BP measurement taken were also not statistically significant between the usual care and intervention groups (Table 1).

The mean of SBP recordings in the intervention group was 7 mm Hg (95% CI 5, 10 mm Hg, P < 0.001) higher than in the usual care group. There was no significant difference in mean of DBP recordings between study groups (IRR 0.3, 95% CI −1.6, 2.3, P = 0.69).

Patients taking BP lowering drugs were more likely (IRR 1.3, 95% CI 1.1, 1.7, P = 0.01) to have a BP lowering drug prescribed in the treatment group, compared to the usual care group (Table 1). There was a trend toward patients taking BP lowering drugs being more likely to receive new BP lowering drugs (IRR 1.7, 95% CI 0.95, 2.89, P = 0.07) if they were in the intervention group, but there was no difference between groups in dosage adjustments made.

In univariable analysis, terminal digit preference was not associated with any prescribing behavior but both DBP and SBP were positively associated with prescribing a new or existing antihypertensive drug (data not shown). Table 2 gives the results of the post hoc analyses exploring mediators of changes in prescribing behavior, through examining the associations

### Table 1 | Characteristics of patients measured in intervention and usual care practices in postintervention audit

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual care</th>
<th>Intervention</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients (n = 1,486)</td>
<td>(n = 1,869)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (56.0 (19.6))</td>
<td>55.8 (19.3)</td>
<td>0.77</td>
<td></td>
</tr>
<tr>
<td>Male (42.6)</td>
<td>41.9</td>
<td>0.68</td>
<td></td>
</tr>
<tr>
<td>Blood pressure measured at visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of BP recordings 1</td>
<td>21.2</td>
<td>24.8</td>
<td>0.65a</td>
</tr>
<tr>
<td>&gt;1</td>
<td>0.5</td>
<td>2.2</td>
<td></td>
</tr>
<tr>
<td>Terminal digit of SBP reading = 0</td>
<td></td>
<td></td>
<td>&lt;0.001c</td>
</tr>
<tr>
<td>Terminal digit of DBP reading = 0</td>
<td></td>
<td></td>
<td>&lt;0.001c</td>
</tr>
<tr>
<td>Mean SBP (132 (18))</td>
<td>139 (20)</td>
<td>&lt;0.001c</td>
<td></td>
</tr>
<tr>
<td>Mean DBP (79 (11))</td>
<td>79 (14)</td>
<td>0.69c</td>
<td></td>
</tr>
<tr>
<td>On antihypertensive treatment</td>
<td>41.2</td>
<td>38.7</td>
<td></td>
</tr>
<tr>
<td>Blood pressure recorded at visit</td>
<td>31.1</td>
<td>38.2</td>
<td>0.18c</td>
</tr>
<tr>
<td>Number of BP recordings 1</td>
<td>30.3</td>
<td>33.5</td>
<td>0.35a</td>
</tr>
<tr>
<td>&gt;1</td>
<td>1.1</td>
<td>4.7</td>
<td></td>
</tr>
<tr>
<td>BP lowering drug prescribed</td>
<td>21.9</td>
<td>29.3</td>
<td>0.01c</td>
</tr>
<tr>
<td>New BP lowering drug prescribed</td>
<td>4.3</td>
<td>7.1</td>
<td>0.07c</td>
</tr>
<tr>
<td>Dose adjustment of BP lowering drug</td>
<td>3.4</td>
<td>2.4</td>
<td>0.82c</td>
</tr>
</tbody>
</table>

Mean (s.d.) or %BP: blood pressure; DBP, diastolic blood pressure; FP, family physician; SBP, systolic blood pressure.

Table 2 | IRR (95% CIs) for potential mediators of the effect of intervention on prescribing behavior

<table>
<thead>
<tr>
<th>Predictor</th>
<th>BP lowering drug prescribed</th>
<th>P value</th>
<th>New drug prescribed</th>
<th>P value</th>
<th>Dose adjustment of BP</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digit preference SBP</td>
<td>1.03 (0.77, 1.37)</td>
<td>0.88</td>
<td>1.31 (0.64, 2.71)</td>
<td>0.38</td>
<td>0.61 (0.25, 1.52)</td>
<td>0.25</td>
</tr>
<tr>
<td>Digit preference DBP</td>
<td>0.83 (0.61, 1.13)</td>
<td>0.22</td>
<td>1.15 (0.59, 2.26)</td>
<td>0.66</td>
<td>1.05 (0.43, 2.57)</td>
<td>0.85</td>
</tr>
<tr>
<td>SBP (per 10 mm Hg)</td>
<td>1.11 (1.02–1.21)</td>
<td>0.02</td>
<td>1.44 (1.22, 1.71)</td>
<td>&lt;0.001</td>
<td>1.17 (0.92–1.57)</td>
<td>0.15</td>
</tr>
<tr>
<td>DBP (per 10 mm Hg)</td>
<td>1.15 (1.00–1.32)</td>
<td>0.05</td>
<td>1.21 (0.92, 1.57)</td>
<td>0.17</td>
<td>1.01 (0.68–1.49)</td>
<td>0.98</td>
</tr>
</tbody>
</table>

Relative risks were calculated using IRRs from mixed multilevel Poisson regression. IRR measures the ratio of the event rate (prescribing behavior) in the intervention group divided by the event rate in the usual care group and is a consistent estimator of relative risk. Note: There was no independent effect of study arm allocation (intervention or usual care) on any prescribing behavior in these models.

CI, confidence interval; DBP, diastolic blood pressure; IRR, incidence rate ratio; SBP, systolic blood pressure.

Adjusted for age, sex, DBP, and SBP and treatment arm. Adjusted for age, sex, DBP, or SBP (as appropriate) and treatment arm. IRR estimates are per 10 mm Hg change in SBP or DBP.
between prescribing behaviors and terminal digit preference, SBP and DBP, and allocation arm. SBP was an independent predictor of antihypertensive drug prescription and of the prescription of a new antihypertensive drug, but not of dose adjustment to an existing antihypertensive drug. DBP was an independent predictor only of the prescription of an antihypertensive drug. There was no independent effect of treatment allocation on prescribing behavior in this multivariable analysis, demonstrating that the intervention effect was mediated through BP levels.

To investigate this further, we looked at the mean SBP distributions between the intervention and usual care groups (Figure 3). The distributions can be described as having the appearance of the broad smile of a normal distribution (intervention) vs. a gap-toothed malocclusion grin of a skewed distribution (usual care). Frequency counts were higher for terminal “0s” than adjacent terminal “5s” and the distribution was skewed to the right ($P < 0.001$).

**DISCUSSION**

In our study, oscillometric machine BP measurements markedly reduced terminal digit preference and resulted in the recording of higher mean SBP. Importantly, their use also increased antihypertensive prescribing. This was mediated through the effect of the recording of higher mean SBP, independent of the reduction in terminal digit preference.

A strength of our study is its prospective controlled design and this may explain differences between our findings and those of a previous observational study. This UK study did not demonstrate any differences in SBP before and after introducing automated sphygmomanometers. However, this was an uncontrolled study, which is likely to be confounded, for example by treating to lower targets and population trends in mean BPs. Our findings are consistent with a cross-sectional study of 85 US primary care practices that demonstrated that practices with high terminal digit preference (44.6% SBP) had lower SBP and lower odds of antihypertensive medication prescription.

Wingfield and others looked at terminal digit preference and single number preference in the Syst-Eur trial. They found an initial terminal zero preference of 42.4% which improved to 22% which they attributed to their quality control procedures. Their observed threshold bias of 148 mm Hg systolic, however, persisted (goal BP was <150 mm Hg). This intervention (monitoring and feedback), however, was uncontrolled. They concluded that "automated devices should ideally be employed to avoid these problems." Our study showed a marked reduction in digit preference though our data suggests that to remove all human measurement bias, fully automated machines with computer interface and downloading is required.

Despite the major role of hypertension as a risk factor for cardiovascular disease, hypertension is acknowledged as being inadequately managed throughout the world. For example, >60% of Australians taking antihypertensive medication had BP readings above the normal range. The effect seen in CRAB on antihypertensive prescribing was substantial (7.4%). The effect on the prescribing of new medication, while modest (2.8%), is of clinical and public health significance when compared to the level of untreated hypertension in individuals at risk. In Australia, an estimated 7% of the population has both untreated hypertension and a cardiovascular risk elevation making treatment likely to be beneficial. The finding that the use of automated oscillometric BP measuring devices led to increases in FPs overall prescribing of antihypertensive drugs, with a trend to an increase in the prescribing of new drugs demonstrates that the introduction of these machines may be a relatively simple and inexpensive way to improve management of hypertension and has potential to improve cardiovascular outcomes.

Although the use of automated BP devices resulted in a reduction in digit preference, digit preference itself did not influence prescribing behaviors (Table 2). In our post hoc analyses, in models of prescribing behavior containing both SBP and arm allocation, SBP was a statistically significant predictor of both prescribing antihypertensive drugs and the commencement of new antihypertensive therapy, but allocation arm was not (Table 2). Hence, the level of SBP is the main mediator of changes in prescribing behavior, and underlines the importance of ensuring the accuracy of the measuring and recording of BP readings.

SBP readings were higher in the intervention group. There are a number of possible mechanisms for this. The reduction in digit preference may have eliminated rounding down and threshold bias, the recording of BP preferentially below treatment thresholds. A reduction in other forms of observer error such as eliminating auscultatory gap and rapid deflation may also have contributed.

**Study limitations**

As contemporaneous “gold standard” measurements were not taken, it is not possible to determine whether poorly maintained manual sphygmomanometers systematically underestimated or that oscillometric devices overestimated the true SBP. In validation studies of the OMRON device
used in CRAB, there were no statistically significant differences in mean SBP or DBP measurements compared to mercury machines although Elliot et al. subsequently reported significant differences (SBP +2.12 mm Hg and DBP −2.36 mm Hg). Given that hypertension is frequently undertreated, increasing treatment is more likely to be beneficial at a population level than a cause for concern. We do not have longitudinal data examining the long-term effects of changes in prescribing behavior on BP levels and cardiovascular outcomes, so while we postulate that these changes will lead to positive clinical outcomes, this cannot be demonstrated conclusively in this study. The possibility of a Hawthorne effect, where knowledge of study participation alters participant behavior, is reduced by our study design. This is through the randomized controlled design, the use of research nurses to collect audit data so that data collection would not influence FP behavior, and the use of a run-in phase to reduce the initial novelty effect of introducing automated sphygmomanometers.

The use of automated oscillometric BP measuring devices compared with usual manual devices led to increases in overall prescribing of antihypertensive drugs and reduced digit preference. The former was due to higher SBP recordings rather than the latter as we had postulated. Such devices reduce the systematic biases that appear to be present in manual BP measurements. Thus, the introduction of these machines as a consequence of phasing out the use of mercury may be a relatively simple and inexpensive way to improve management of hypertension and has potential to improve cardiovascular outcomes internationally.

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