

Accuracy of the OMRON M4 Automatic Sphygmomanometer.

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Andrew A J Clarke 3522593. School of Health Sciences. Faculty of Human development.

BSc(Clin Sci).

Student osteopath-Victoria University.

Cameron Gosling

B.AppSc (HM),Grad. Dip (Ex Rehab), M.AppSc

Lecturer-Victoria Universty.

Melainie Cameron

BAppSc(Ost), MHSc.

Senior Lecturer-Victoria University.

Correspondence author:

Cameron Gosling

Correspondence address:

PO Box 14428 Melbourne City

MC 8001 AUS

Ph: (03) 9919 1290

Email: cameron.gosling@vu.edu.au

ABSTRACT

The Omron M4 (AS) is an upper arm automatic sphygmomanometer that has not been conclusively validated in clinical trials. The aim of this research was to determine whether the Omron M4 was accurate enough for clinical use.

Sixty two young, apparently healthy participants were recruited. Participants had their blood pressure (BP) taken once with the AS and once with a mercury sphygmomanometer (MS) in random order. Results were compared against The British Hypertension Society (BHS), and The Association for the Advancement of Medical Instrumentation (AAMI) protocols for evaluation of automatic sphygmomanometers.

The Pearson's r correlation between the AS and the MS demonstrated a moderately positive relationship for the systolic BP readings and a weakly positive relationship for the diastolic readings. The AS achieved a pass according to the AAMI standards and an overall grading of C (failed) according to the BHS assessment criteria. We concluded that the Omron M4 is questionable rating according to previously stated guidelines.

INDEXING TERMS

Omron M4/ Automatic sphygmomanometer/ Automatic blood pressure monitor.

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INTRODUCTION

Automatic sphygmomanometers (AS) are becoming widely used in medical settings and in the home for patient self-measurement of blood pressure (BP). Regardless of whether a layperson or a medical professional uses this equipment, accuracy is of the utmost importance. BP is a useful predictor of an individual's future health and is an indicator of the present clinical condition of a patient.¹ Inaccurate BP readings may result in overestimation or underestimation of a patient's true BP, leading to either a costly outcome of over prescription of anti-hypertensive medication or a failure to address hypertension, which is a somewhat modifiable risk factor for cardiovascular disease.¹

The Omron M4 is an upper arm AS designed for ease of use in either the home or the clinical environment. This AS has not yet been conclusively validated by clinical trials according to an investigation of the current literature.^{2 3 4}

The aim of this research was to determine whether the Omron M4 (AS) was accurate enough to be used as a clinical tool according to the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI).

METHODS

Sixty two participants were voluntarily recruited from the student population at Victoria University (VU). Each participant provided written informed consent, and the Victoria University Human Research Ethics committee approved the study. Participants were young and apparently healthy (24 ± 6 yrs, 170 ± 9 cm, 66 ± 11 kg). Volunteers were excluded if they had smoked cigarettes or ingested caffeinated drinks within 2 hours of

testing, or had exercised on the day of testing. Participants were asked to sit quietly in a silent room for ten minutes to allow their BP to drop to a resting level before having their BP measured. Each participant had their BP taken once with each of two sphygmomanometers - the Omron M4 AS and the Kosan mercury sphygmomanometer. Mercury sphygmomanometers are the gold standard for indirect measurement of blood pressure. They are of a simple design that rarely needs repair, and have been thoroughly validated against direct intra-arterial blood pressure.⁵

Half of the participants had their BP measured first with the AS, and the other half had their BP measured first with the MS. This alternation of measurements was undertaken to remove any order effect.

Assessment criteria

O'Brien et al² indicated the two most widely used protocols for the evaluation of automatic sphygmomanometers are the British Hypertension Society (BHS) protocol and the standard set by the US Association for the Advancement of Medical Instrumentation (AAMI).^{6,7} These protocols can be applied individually, however, O'Brien et al⁸ stated that the two protocols can be reconciled and should both be used in validation studies.

The AAMI protocol dictates the test device must not differ from the mercury sphygmomanometer by a mean difference >5 mm Hg or a standard deviation >8 mm Hg.⁷ The BHS protocol dictates that a test device is suitable for clinical practice when at least 60% of the readings fall within 5mmHg, 85% fall within 10mm Hg, and 95% within 15 mm Hg of the manual sphygmomanometer.⁴ The data acquired has been expressed as group mean \pm SD and as percentages and then compared to the AAMI and BHS

standards. O'Brien et al² proposed a further set of criteria that they used to designate devices according to their accuracy. They classed a device as recommended if it fulfilled the AAMI criteria for both systolic and diastolic pressures and received a grade of A or B (see table 1) under the BHS protocol for both systolic and diastolic blood pressures. A device was classed as not recommended if it failed the AAMI criteria for either systolic or diastolic pressure and achieved a grade of C or D (see table 1) for either systolic or diastolic pressure under the BHS protocol. A questionable recommendation was made when a device fulfilled the criteria of one protocol but not the other. We have used the same criteria in assessing the Omron M4.

Data Management

The data was expressed as mean \pm standard deviation, and percentage agreement. A Pearson's r correlation was used to assess how closely the data from the MS was related to the data from the AS.

RESULTS

The Omron M4 and MS were compared using the AAMI standards. After analysis it was found that there was an average difference of 1.5 ± 7.6 mmHg for systolic BP and an average difference of 3.8 ± 7.8 mmHg for diastolic BP, between the AS and the MS. The above-mentioned discrepancy did not exceed an average of 5 mmHg with a standard deviation not in excess of 8 mmHg and therefore satisfied the AAMI requirements.

The accuracy of the AS was also tested according to the standards of the British Hypertension Society. Forty five% of systolic and 52% of diastolic readings fell within 5

mmHg of the MS. 81% of systolic and 82% of diastolic readings fell within 10 mmHg of the MS. 97% of systolic and 90% of diastolic readings fell within 15 mmHg of the MS. The AS was inaccurate in all the ranges except for the 97% of readings that fell within 15 mmHg of the MS. Therefore on the whole the automatic device achieved an overall grading of C according to the BHS (Table1).

The systolic and diastolic readings for the AS were compared with the MS. Pearson's r for the systolic reading was 0.78 (r squared = 0.60). Pearson's r for the diastolic readings was 0.43 (r squared = 0.185) (figures 1&2)

DISCUSSION

The Pearson's r correlation analysis indicated that there was a moderately positive relationship between the systolic readings and a weakly positive relationship between the diastolic readings for AS compared with MS. The Omron achieved a pass according to the AAMI standards and an overall grading of C according to the BHS. After applying the criteria set forth by O'Brien et al³ the M4 was designated as questionable in its accuracy. This is because it passed the AAMI criteria and failed the BHS criteria.

These findings are supported by O'Brien et al² who in a review of the literature available on several different automatic sphygmomanometers also gave the Omron M4 a questionable recommendation. This was based on the results of a study by Artigao et al.³ Only the abstract of this article has been published, and in this abstract the authors concluded that the Omron M4 was fit to be recommended for clinical use. The reason O'Brien et al² only gave the Omron a questionable recommendation is that there was doubt about the strength of the evidence available for this device as with only the abstract

of Artigao et al's³ study being available it was not possible to determine their methods or scrutinize their results.

The only other study available on the Omron M4 was carried out by Naschitz et al,⁴ the results of which conflicted with the results of our study. They utilized the rapid method for evaluation of automatic blood pressure measurement devices (READ method). The READ is based on multiple blood pressure measurements taken at rest and during postural challenges. This simulates a wide range of different blood pressures and only requires the recruitment of a small number of participants. In Naschitz et al's⁵ study only 4 participants were involved. The authors found that the M4 invariably underestimated the diastolic blood pressure and unpredictably over or underestimated the systolic blood pressure. They concluded that the M4 was inaccurate and could not be recommended for clinical use. This conclusion may be more realistic than our own in relation to the varied BP ranges experienced in clinical practice. We measured a healthy, young and relatively homogenous group of participants, which may have contributed to the questionable recommendation we have concluded.

According to the British Hypertension Society and the AAMI standards, we have found that the Omron M4 automatic sphygmomanometer can only be given a questionable recommendation for clinical use. We also believe that the majority of the evidence available concurs with this conclusion. Furthermore it is our opinion that there are many other more accurate machines than the Omron M4 available to the public, and recommend that anyone wanting to buy an automatic sphygmomanometer research the evidence available before making their purchase.

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Figure 1 Diastolic BP readings from Omron M4 vs. diastolic BP readings from the manual sphygmomanometer

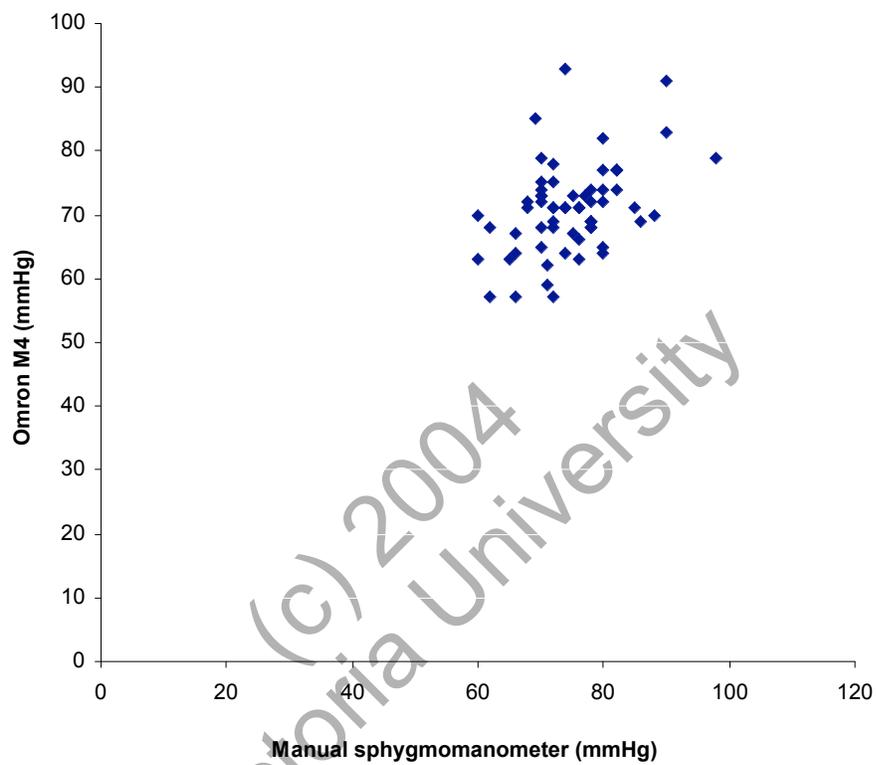


Figure 2 Systolic BP readings from the Omron M4 vs. systolic BP readings from the manual sphygmomanometer

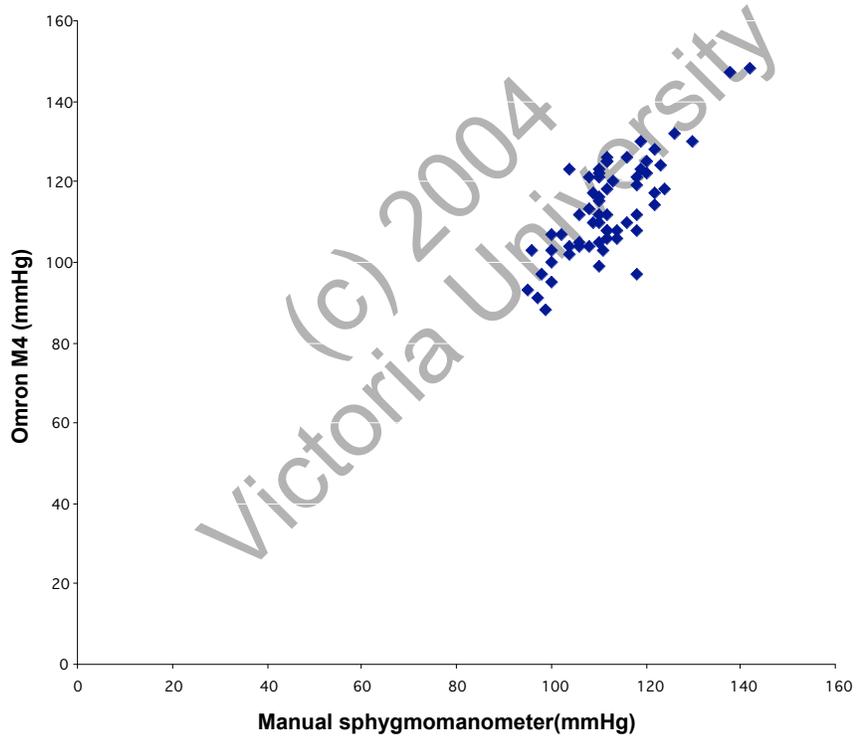


Table 1 Percentage of Omron M4 BP readings lying within 5mmHg, 10mmHg and 15mmHg of manual sphygmomanometer BP readings, and the BHS grading system for automatic sphygmomanometers

	<5mmHg of MS	<10mmHg of MS	<15mmHg of MS
Systolic BP from AS	45	81	97
Diastolic BP form AS	52	82	90
Grading	A 60 B 50 C 40 D worse than C	85 75 65	95 90 85

(For the Omron M4 to achieve one of the above grades all three percentages for systolic and diastolic BP must be greater than or equal to the percentages shown for that specific grade)

APPENDIX 1

INFORMATION TO PARTICIPANTS

PROJECT

Accuracy of the OMRON M4 automatic sphygmomanometer.

INVESTIGATORS

Andrew Clarke, Cameron Gosling and Melainie Cameron.

LOCATION

Victoria University Osteopathic Medicine Clinic,
Level 4,
301 Flinders Lane,
Melbourne.

PURPOSE AND PLAN OF THE STUDY

You are invited to participate in a study to test the accuracy of a blood pressure measuring device. Testing will involve one session taking approximately 20 minutes. A time will be arranged before testing begins to have any questions answered and for you to bring in the consent form.

The testing session entails avoiding the consumption of caffeine and cigarettes, and not exercising on the day of testing. On the testing day you will be asked to rest in a room for 10-15 minutes before a qualified and experienced operator will enter the room and take your blood pressure. This person will then take your blood pressure again. At this time you will be free to leave.

RISKS AND INCONVENIENCES

There is a risk that you may feel some pain or bruising in your arm when the operator takes your blood pressure. However this risk is very small due to the fact that only qualified and experienced practitioners will be taking your blood pressure. If the aforementioned occur you will be removed from the study.

VOLUNTARY PARTICIPATION

Participation in this study is entirely voluntary. You can withdraw from the study at any time, for any reason, without prejudice.

CONFIDENTIALITY

Only the investigators (as listed on the front page) will be allowed to access information that identifies you by name. All results will be totally confidential. No person will be identified by name in the report produced following testing.

QUESTIONS

If at any time you have any questions regarding the study, please feel free to contact the principle investigator or co-investigators on the following numbers.

Andrew Clarke	92481111
Cameron Gosling	92481290
Melainie Cameron	92481149

If you have any questions regarding the ethics of the study, or your rights as a participant, please contact the Victoria University Human Research Ethics Secretary on 96884710.

APENDIX 2

Victoria University of Technology

Consent Form for Participants Involved in Research

INFORMATION TO PARTICIPANTS:

We would like to invite you to be a part of a study assessing the accuracy of a blood pressure measuring device.

CERTIFICATION BY SUBJECT

I, _____
of _____

certify that I am aged over 18 and that I am voluntarily giving my consent to participate in the experiment entitled: "Accuracy of the OMRON M4 automatic sphygmomanometer", being conducted at Victoria University of Technology, Level four, 301 Flinders Lane, Melbourne by: Andrew Clarke, Cameron Gosling and Melainie Cameron.

I certify that the objectives of the investigation, together with any risks to be associated with the procedures listed here, have been fully explained to me by Andrew Clarke, Cameron Gosling or Melainie Cameron and that I freely consent to participate in this study.

Procedures:

Testing will involves one testing session taking approximately 20 minutes. A time will be arranged before testing begins to have any questions answered and for me to bring in the consent form.

The testing session entails avoiding the consumption of caffeine and cigarettes, and not exercising on the days of testing. On the testing day I will be asked to rest in a room for

10-15 minutes before a qualified and experienced operator will enter the room and take my blood pressure. This person will then take my blood pressure again. At this time I will be free to leave.

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this experiment at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed:

Witness other than the experimenter:

Date:

.....

Any queries about your participation in this project may be directed to the researcher (Name: Mr. Andrew Clarke, ph. 92481111, Mr. Cameron Gosling, ph. 92481290 or Dr. Melainie Cameron, ph. 92481149). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MC, Melbourne, 8001 (telephone no: 03-9688 4710).

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