

Accuracy of an automatic blood pressure device: the Omron HEM403C

Blood pressure (BP) measurement is particularly important for patients with hypertension in which small differences in the BP readings may dictate changes in diagnostic work-up and treatment, as well as in the prognosis. The extensive use in daily practice of automated sphygmomanometers raises the problem of assessing their accuracy.¹

Walma *et al*² recently reported a study on the accuracy of an automatic BP device, Omron HEM403C. When compared with the Hawksley random-zero sphygmomanometer (HRZS), they found that Omron HEM403C overestimates both systolic (SBP) and diastolic (DBP) readings by approximately 1 ± 9 mm Hg and 4 ± 8 mm Hg, respectively. Although the authors stated that the requirements for agreement between the two methods of both the British Hypertensive Society (BHS)³ and the American Association for the Advancement of Medical Instrumentation (AAMI)⁴

were only marginally fulfilled, they finally concluded that the Omron HEM403C is accurate enough for clinical and research purposes. This conclusion has to be regarded in the light of a number of limitations of the study of Walma *et al*, some of which the authors were aware, such as using the HRZS as a reference, as well as the incomplete distribution for age and BP levels required by the BHS and AAMI protocols. In addition, the authors did not mention the dimensions of the cuffs used, the position in which the BP was measured or the duration of the resting period before the BP measurement.

Some time ago, when looking for BP measuring devices suitable for BP control at home, we also tested the accuracy of the Omron HEM403C. We came to conclusions more or less contradictory to those of Walma *et al*. In 369 outclinic patients, all under long-term anti-hypertensive treatment, we compared the Omron with the standard sphygmomanometer. All BP readings were carried out by the same experienced observer. In all patients the BP was measured at the right arm, three times, after at least 10 min

of rest in the lying position. We used two devices: the Omron HEM403C and a legally stamped mercury sphygmomanometer, Erkameter^R 300, connected by an Y rubber tube to one cuff (14 × 22 cm) fitted around the arm of the patient. Both instruments were recently calibrated and were functioning appropriately. Patients with an arm circumference of > 33 cm were excluded.

The results were as follows: the first reading were $150/91 \pm 21/10$ and $144/90 \pm 20/11$ mm Hg (mean \pm s.d.) with the Erkameter and Omron, respectively. For the second reading the respective figures were $151/91 \pm 21/10$ and $144/88 \pm 20/11$ and for the third reading $152/90 \pm 22/10$ and $143/88 \pm 20/11$ mm Hg. Since for both methods there was no significant difference between the three subsequent readings, we calculated the mean of all three readings per patient and averaged them for the 369 patients ($151.1/90.5 \pm 20.8/9.6$ and $143.8/88.6 \pm 19.5/10.7$ mm Hg). This difference between the two devices was highly significant ($P < 0.0001$) for both SBP and DBP. Next, we determined the percentages of simultaneous readings in which

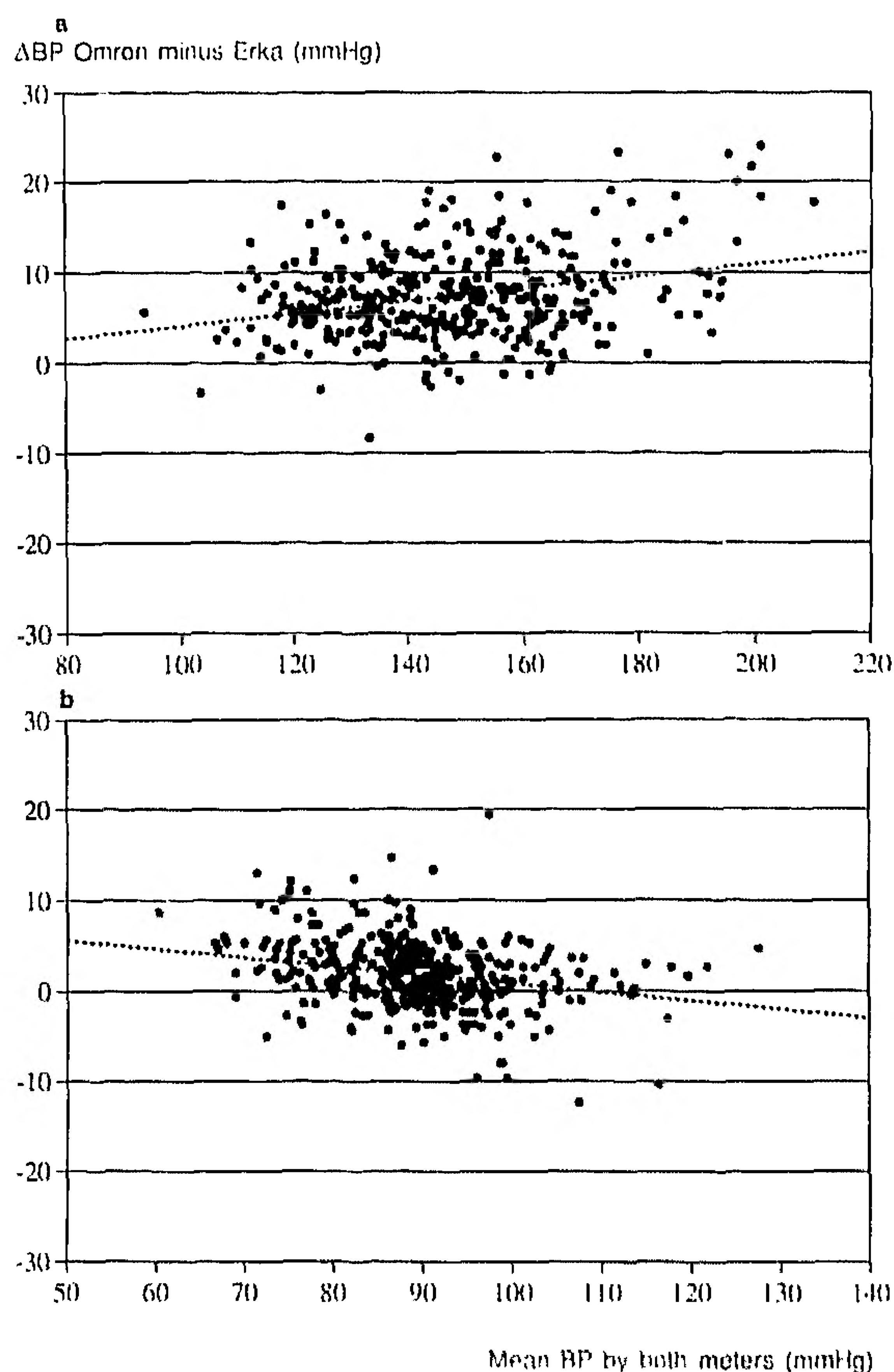


Figure 1 Difference against mean for systolic (a) and diastolic (b) blood pressure (BP) readings with the Omron HEM403C and Erkameter^R 300. Every dot represents the mean of three BP readings obtained in the same subject. The regression lines are plotted in the figures as dotted lines

the difference was within 5, 10 and 15 mmHg, again for both SBP and DBP. For SBP the respective percentages were 7, 77 and 93 and for the DBP 83, 98 and 100. Figure 1 shows the individual values for the BP readings. The formulas for the regression lines are $y = 0.07 \text{ (SBP)} - 2.7$ and $y = -0.1 \text{ (DBP)} + 10.3$, clearly different from the figure in the paper of Walma *et al.*

Thus, in our sample of 369 out-clinic hypertensives, the Omron

significantly underestimated both SBP and DBP. The difference in SBP also has clinical relevance. When looked at separately, the difference we noticed in DBP is acceptable and a grade A would be received by the Omron device according to BHS grading criteria for simultaneous measurements. However, the difference in the SBP between the two devices is unacceptably high and a BHS grade D would be received by the Omron device.

So, contrasting data are available for the accuracy of the Omron HEM403C. Neither our study nor the study of Walma and another study⁵ showed an accuracy of the device in complete agreement with the BHS and AAIM requirements. However, in none of these studies was the BHS or AAIM protocols for the evaluation of automated BP measuring devices followed completely. We conclude that more carefully controlled studies are needed before recommending the Omron HEM403C for clinical and research purposes.

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