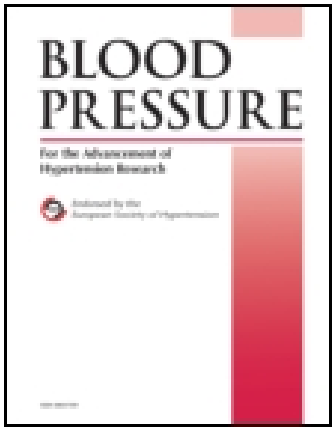

Blood Pressure
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/iblo20

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Published online: 08 May 2015.

To cite this article: S. Bardak, K. Turgutalp, T. Özcan, Z. E. Eser, Y. Gözükara, S. Demir & A. Kiykim (2015) How do we measure blood pressure at home?, Blood Pressure, 24:3, 174-177

To link to this article: http://dx.doi.org/10.3109/08037051.2014.997082

Blood Pressure, 2015; 24: 174–177

informa
healthcare

ORIGINAL ARTICLE

How do we measure blood pressure at home?

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Abstract

Background. Home blood pressure monitoring (HBPM) is one of the measures that increases compliance with antihypertensive therapy. HBPM requires a proper measurement technique as well as an accurate sphygmomanometer. The aim of this study was to assess the characteristics of home sphygmomanometers (HS) in a big city in Turkey. *Subjects and method.* We assessed the HS of hypertensive patients ($n = 452$; male: 253, female: 199) who were examined for the first time in our outpatient center. General evaluation of HS included trademark, model, device's age, cuff size, validation and calibration status. *Results.* We interviewed 452 patients and 452 HS were identified. The most common factors affecting the patients' choice for the type and model of the HS were its simplicity and ease of use (28.2%), followed by advertisements (44%), physician's advice (19.3%) and the belief in accurate measurement (< 1%). All patients were unaware of validation and calibration of their devices. *Conclusion.* Awareness of both patients and physicians about the validation status of HS is not enough. Some complaints from patients may be associated with using non-validated HS. There is a need for a policy or standard criteria for HS.

Key Words: *Blood pressure, home sphygmomanometer, hypertension, validation*

Introduction

Hypertension is the leading risk factor for cardiovascular disease worldwide (1). Accurate blood pressure (BP) measurement is required for proper diagnosis and control of hypertension. Home BP monitoring (HBPM) is one of the measures that increases patient compliance with the treatment, and has great potential to improve hypertension control (2). HBPM is being increasingly used in many countries and is well accepted by hypertensive patients (3).

Proper technique and an accurate sphygmomanometer are essential for the long-term follow-up of hypertension (3). However, several problems exist regarding the application of the technique in clinical practice. The inaccuracy of most devices used for HBPM (4) and the subjective nature of patients' HBPM recordings (misreporting) (5) are major limitations that preclude the reliable and unbiased estimation of the level of BP at home.

On the other hand, inaccuracy of home sphygmomanometers (HS) is actually a common problem, which is often ignored. Recently, a national cross-sectional study carried out by Turkish Society of Hypertension and Renal Diseases demonstrated that use of non-validated HS has become widespread in our country, and most of the patients (94%) did not report their BP measurements to the physician (6). Furthermore, there is no policy or standard criteria for BP measurement devices in Turkey.

The aim of this study was to assess the characteristics of HS in a big city in Turkey.

Patients and methods

The study design was approved by local Human Research Ethics Committee. Written informed consent for participation in the study was obtained from each subject. Four hundred and fifty-two hypertensive patients having HS who admitted for the first time to our outpatient University Hospital Hypertension Clinic were included to the study. Patients were administered a questionnaire designed to assess the reason for purchasing the device, place

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(Received 19 June 2014; accepted 3 December 2014)

ISSN 0803-7051 print/ISSN 1651-1999 online
DOI: 10.3109/08037051.2014.997082

where it was purchased from and reasons for choosing a particular brand, people who suggested this device, age of the device and type of the device (worn on the wrist, upper arm etc.). We also asked if they were informed about the use of the device, either at the time of sale or after, and if the device had ever been evaluated for accuracy since after sale. General evaluation of the device included basic features, validation status and cuff size. Both the manufacturer and model of devices were recorded. Questionnaires were applied to subjects face to face by two nephrologists (AK, KT) and a cardiologist (TO). HS were also evaluated by these investigators.

All of the patients brought their HS to the clinic for the evaluation. Not only trademark and model of the HS were recorded but also all of them were checked for calibration status, cuff rupture, manometer damage, battery problems and cuff size. We also recorded the patients' complaints including palpitation, dizziness and headache. We advised all our patients to switch from their old devices, which were determined as non-validated to validated ones. Then, we suggested patients to measure their BP with both old and new devices throughout one month in order to compare measurements. After this period, we checked the patients for their previous complaints.

Evaluation of the validation

Validation of devices was evaluated in accordance to the Dabl® Educational Trust (DETW) (Dabl® Educational Trust: http://www.dableducational.org; accessed in October 2013) website. The recommended devices were considered validated, and unrecommended and questionable devices were considered non-validated. On the other hand, a validation study for each non-validated device was checked in the journals indexed in science citation index and science citation index–expanded.

In order to evaluate patients' complaints before and after the switch of HS, a paired samples *t*-test was used, and a p-value < 0.05 was accepted as statistically significant.

Results

Mersin, with 2.1 million people, is a big city in Turkey. Interviews were conducted with 452 hypertensive patients (253 male; 199 female; aged 18–77). Mean hypertension duration of the patients was 7.9 ± 4.1 years. All patients had been treated with antihypertensive medication(s). Mean systolic and diastolic BP were found to be 132.2 ± 5.1 and 91.3 ± 3.8 mmHg with their older HS, respectively.

Nonetheless, we found that 12.6% ($n = 32$), 16.2% ($n = 41$) and 9.8% ($n = 25$) of all male patients, and 8.0% ($n = 16$), 10.5% ($n = 21$) and 19.0% ($n = 38$) of all female patients had intermittent headache, dizziness and intermittent palpitation, respectively (Table I). The number of patients with comorbid conditions was shown in Figure 1. Three hundred and seventy-two (82.3%) patients had at least one comorbid condition.

A total of 452 HS were evaluated, and 24 different brands and their various models were determined. Both the name of manufacturers and model of all devices were recorded. Types of HS were shown in Figure 2. Two hundred and sixty-nine (85 of them worn on the upper arm and 184 of them worn on the wrist) of the HS were electronic, whereas 149 of the devices were aneroid and 34 of devices were other kinds. Only 24 devices were found to be "recommended" on DETW. On the other hand, none of them was regularly calibrated. Interestingly, all patients believed that the measurement of their devices was correct.

The most common reasons for preferring the type and model of the HS that had been bought were advertisements and campaigns ($n = 199$, 44.02%), followed by their simplicity and ease of use ($n = 127$, 28.09%), physician advice ($n = 87$, 19.24%), and the others ($n = 39$, 8.6%). None of the HS owners bought the device because of its validity. Interestingly, almost all the evaluated devices were imported from other countries.

The majority of devices ($n = 204$, 45%) had been recommended by their relatives, neighbors and friends. Only a small number of HS ($n = 87$, 19.24%) had been recommended by physicians. All the devices recommended by physicians were non-validated. Furthermore, there were 14 specialists (internist, nephrologist or cardiologist) among these physicians.

Ages of the devices were between 1 month and 20 years (4.35 ± 4.32 years). While the age of 48 devices was found to be between 10 and 20 years, six devices had been used for more than 20 years. Any technical assessment to these devices was not performed during their lifetime.

Table I. Patients' complaints before and after switching non-validated home sphygmomanometers (HS) with validated HS.

	Male patients (n)			Female patients		
Symptoms	Before (n)	After (n)	p	Before (n)	After (n)	p
Headache	32	8	< 0.05	16	6	< 0.05
Dizziness	41	14	< 0.05	21	4	< 0.05
Palpitation	25	5	< 0.05	38	11	< 0.05

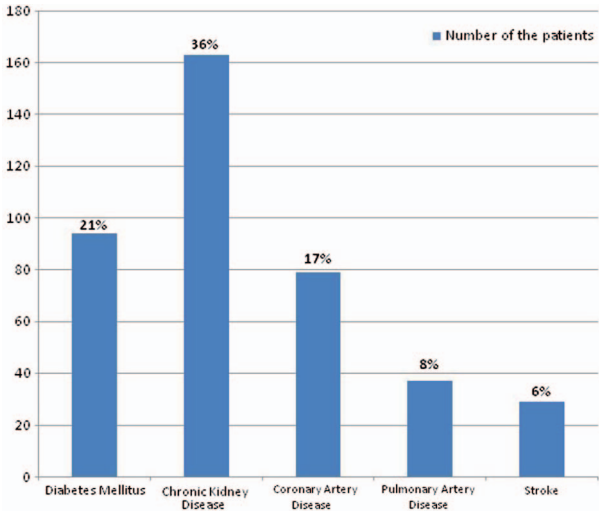

Figure 1. Number of patients with comorbidities ($n = 452$).

Cuff ruptures, battery problems and manometer or monitor damage were detected in 118 devices (26.1%).

Only 35 patients (8%) measured their arterial BP and kept a daily calendar before admitting to the doctor, whereas other patients (92%) did not measure or record their BP values.

Overall, 80.7% (365 of 452) of the patients measured BP when they had headache, whereas only a small number of the patients (19.3%) measured their BP regularly without having any complaint. Interestingly, none of their physicians had inquired about BP measurement techniques.

Although most of the patients agreed with the recommendation to buy new devices ($n = 355$, 78.5%), the rest of them refused to switch their old HS to new ones for various reasons. Some of them declared that they were pleased with their old HS, whereas some could not afford to buy new HS and the others planned to admit to a primary care center for follow-up instead of HBPM.

Three hundred and thirty-five patients who switched their HS were asked for consecutive BP monitorization for 1 month by both their old and new HS. It was demonstrated that about 27% of the patients had similar BP measurements, whereas 61% had higher measurements and 12% had BPs below 115/75 mmHg. After 6 weeks following the changes in treatment strategies, BP goals were achieved.

Symptoms of the patients whose device and antihypertensive therapy had been changed were compared. Before changing the device and the antihypertensive therapy, 12.6% ($n = 32$), 16.2% ($n = 41$) and 9.8% ($n = 25$) of all male patients and 8.0% ($n = 16$), 10.5% ($n = 21$) and 19.0% ($n = 38$) of all female patients had intermittent headache, dizziness and intermittent palpitation, respectively. After changing the device and the antihypertensive therapy, only 3.1% ($n = 8$), 5.5% ($n = 14$) and 1.9% ($n = 5$) of all male patients and 3.0% ($n = 6$), 2.0% ($n = 4$) and 5.5% ($n = 11$) of all female patients had intermittent headache, dizziness and intermittent palpitation, respectively ($p < 0.01$ for all).

Discussion

In Turkey, HS are easily available from a variety of sources such as gross-markets, medical markets, pharmacies and electronic device markets. This study shows that all HS owners and probably some physicians were not aware of the validation status of devices used in our city. This is the first study to evaluate the HS and their owners, who were admitted to the teaching hospital for the first time.

Accurate measurement of home BP with validated devices is important for the diagnosis and treatment of hypertension. Akpolat et al. (7) showed that there is a great difference between validated and non-validated devices regarding accuracy (68% vs 15%, respectively). On the other hand, validated devices should be tested regularly for accuracy. In our study, systolic and diastolic BPs measured by validated HS were found to be higher than measurements performed by non-validated HS. The DETW provide lists of recommended HS that have been validated in accordance with the guidelines of the International Protocol, the British Hypertension

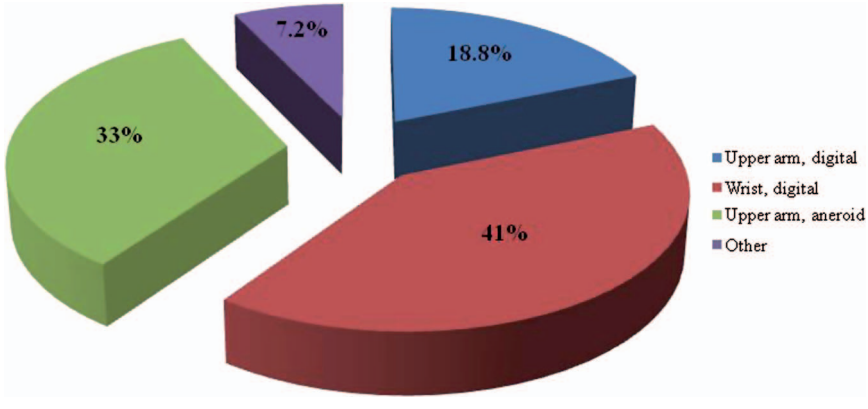

Figure 2. Types of home sphygmomanometers.

Society or the Association for the Advancement of Medical Instrumentation (8). However, most of the devices available in the market have not been evaluated independently for validation (9). Coleman et al. (10) reported that only 2% of currently available BP monitors in the UK have been validated. A'Court et al. (11) reported that many patients now purchase the HS for low-cost, but most of such devices are unacceptable. Similarly, in our study, only 5% of all devices were recommended in DETW. Unfortunately, there is no policy or standard criteria for imported BP measurement devices in our country. In our study, we found that almost all of the devices were imported from other countries. These unreliable HS may causes mistreated hypertension or inappropriate prescribing and adverse events. In fact, various important symptoms of the patients whose device and antihypertensive treatment schedule had been changed were strikingly improved.

In 2008, guidelines on HBPM set by the American Heart Association, American Society of Hypertension and European Society of Hypertension, emphasizing the importance of checking monitors for accuracy (12). In another important study, it was reported that HS should be checked by clinicians according to a practical version of the European Society of Hypertension Protocol, whether they are acceptable or not (13). Unfortunately, in our study, none of physicians had controlled the patients' HS for validation status.

Imai et al. (14) reported that measurements by aneroid HS with the auscultation method are sometimes unreliable and inaccurate. They recommended use of mercury column sphygmomanometer as a gold standard for HBPM. Kikuya et al. (15) reported that BP should be measured at the upper arm; finger-cuff devices and wrist devices should not be used for the assessment of HBPM. Although the wrist devices are inappropriate for HBPM, most HS were wrist devices in our study, whereas only a small proportion of HS were upper arm digital devices. In addition to this, all devices have problems, such as monitor malfunction, leakage of cuff, battery and button malfunction.

A limitation of the study is lack of evaluation of accuracy.

Conclusion

In our city, awareness of both patients and physicians about the validation status of HS is not enough. Some complaints from patients may be associated with use of non-validated HS. Most patients have purchased HS without any prescription from physicians. On the other hand, physicians do not pay enough attention to this issue. There is a need for a policy or standard criteria for HS. All HS sold in markets or medical companies should be certified for validation, and should be calibrated regularly.

Disclosure statement All authors have no conflict of interest of any type.

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