**Title**: Low accuracy of home blood pressure measurement: a multi-centric survey.

**Running title**: Low accuracy of home blood pressure monitoring.

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**Abstract**

Home blood pressure measurement (HBPM) is increasingly common, but its appropriateness has been rarely assessed. We performed a multi-centric survey to evaluate the degree of patients' adherence to current recommendations on HBPM, and investigate potential predictors of a higher-quality self-measurement. A structured questionnaire was administered to 725 Italian outpatient hypertensive subjects (mean age 52.2±14.4y). Overall, ≥10 recommended procedures were followed by 52.8% of the participants; only 1.0% followed all recommendations. 49.7% of the participants rested for ≥5 minutes before the measurement, 36.8% recorded BP more than once in each measurement session, 34.3% used a chair or bed saddle to support their back. Less than 40% of the patients received some form of training by health professionals. At multivariate analysis, patients receiving/reading instructions showed higher-quality HBPM ($p<0.01$). The accuracy of HBPM needs to be improved, and more efforts should be devoted to provide patients' training on HBPM, especially on the less frequently followed recommendations.

## Introduction

Hypertension diagnosis and control depend on the accurate measurement of blood pressure (BP), which is traditionally made by doctors or nurses in clinical settings (office blood pressure monitoring, OBPM) [1]. However, self-monitoring of blood pressure by patients at home (HBPM) is becoming increasingly common [2,3]. In fact, HBPM is recommended by current guidelines for the management of hypertension [4-10] because it may decrease the white coat effect [11], improve patients' compliance to antihypertensive therapy [12], be more reliable than OBPM [6,13-17], and reduce the number of visits [18] and costs associated with OBPM [10,19]. Moreover, some studies showed that BP is often inadequately measured by health professionals, with consequent BP under- or over-estimation and potentially inaccurate drug prescriptions [20-24].

Likewise traditional BP measurement, also HBPM should be accurate and be performed according to existing guidelines [10,24-28]. Several authors highlighted the possible pitfalls occurring during self-measurement [18,27,29], and investigated the reliability of different BP-measuring devices [30-32]. However, the literature on patients' adherence to HBPM recommendations is limited to three surveys performed in one Danish hospital, on a total of 355 subjects [24,33,34]. Also, no study investigated the potential predictors of inaccurate HBPM, which may be crucial to identify proper solutions.

We carried out a multicentric cross-sectional survey to evaluate the degree of adherence to current recommendations on HBPM, and investigate potential predictors of higher-quality HBPM.

## Methods

From April to June 2013, we asked participation to all subjects with a medical diagnosis of hypertension, presenting for ambulatory visits in 3 Italian public hospitals (Ancona, Ascoli Piceno, Chieti). Eligible subjects were older than 17y, received a recommendation to perform HBPM by a general practitioner or a specialist, had no cognitive disease and provided written informed consent. The study protocol was approved by the Ethics Committee of the coordinating center in Chieti. Each participant was requested to perform a self-measurement, and the procedure was observed by a nurse. Such a nurse was previously

trained to record the level of adherence to current guidelines on HBPM using a structured questionnaire (reported as online supplementary content).

The questionnaire included 15 items, which were designed to evaluate whether the patient followed or not 15 specific recommendations included in current Italian guidelines on HBPM [28]. The questionnaire also included a few items collecting information on the hospital unit, eventual instructions received by the patient, type of device typically used for self-measurement, patients' age, gender, marital status and educational level.

To derive a proxy of the overall adherence to HBPM guidelines, we created a global quality score summing up the answers to each of the 15 items. We assigned one point for each positive answer (adherence met) and zero point for each negative answer (adherence not met). Higher scores indicated higher adherence to guidelines: the maximum possible value (15) meant that during HBPM patients followed all the recommended procedures.

We evaluated the potential predictors of the level of adherence to guidelines using random-effect linear regression, using center as cluster variable. All covariates were included in the model a priori. Multicollinearity, interactions and higher power terms were tested for all covariates. Because the number of missing data was very small (n=4), no missing imputation technique was adopted.

Statistical significance was defined as a two-sided p-value<0.05, and all analyses were performed using Stata 11.1 (Stata Corp., College Station, Texas, 2009).

## Results

*Characteristics of the sample and procedures (Table 1)*

Participation was asked to 771 eligible hypertensive patients and obtained from 725 (mean age 52.2±14.4y; males 49.5%; diabetics 12.7%; 29.4% had dyslipidemia). 97.1% of the participants were assuming antihypertensive medications, since 11.3 years on average: Angiotensin Converting Enzyme inhibitors (45.9%), Beta-blockers (42.3%), Calcium-Channel blockers (41.0%), diuretics (30.8%), and/or alpha blockers (9.0%).

More than half of the patients either received no instructions at all on how to perform HBPM (28.8%) or read the instructions by their selves (25.0%). When somebody did care about training the patients, this

was most commonly a physician (24.0%). More than 60% of patients measured their BP occasionally, without following a fixed schedule. The most frequent devices used for HBPM were electronic, automatic (50.8%) and semi-automatic (24.7%).

*Adherence to home blood pressure monitoring guidelines (Table 2)*

Of the 15 recommended practices, 10 were followed by more than 60% of patients. Five recommendations, however, were followed by less than half. In particular, 32.4% of the participants performed HBPM at the same hour; 36.8% recorded BP more than once in each measurement session; 27.4% kept a diary; 34.3% used a chair or bed saddle to support their back during the procedure; and 49.7% rested for ≥5 minutes before the measurement. Overall, ≥8 of the 15 procedures were followed by 80.3% of the participants; ≥10 by 52.8%; ≥12 by 17.0%, and only 1.0% followed all of the 15 recommended practices.

*Predictors of higher-quality home blood pressure monitoring (Table 3)*

At multivariate analysis, the only variable that was independently associated with the level of adherence to guidelines on HBPM was the source of instructions on the procedure. As compared with subjects who received no instructions at all, those who received information by doctors and pharmacists, and who read the instructions by their selves were significantly more likely to conduct a higher quality HBPM (all $p<0.01$). No significant improvement was observed when the instructions were provided by a nurse.

**Discussion**

In Northern Italy [35], as well as in other Western countries [36,37], it has been estimated that most outpatient hypertensive subjects - up to 75% - are regularly performing HBPM. However, only three Danish assessments of the appropriateness of HBPM are available so far [22,31,32].

In this sample of hypertensive subjects, the level of adherence to current guidelines on HBPM was not univocal: some of the recommended practices for HBPM were followed by a large proportion of patients (use of the same arm and body position, proper choice of cuff, silent room and patient, correct arm and body position, use of arm supports, no clothes over cuff), whereas patients' compliance to other recommendations was unacceptably low. In particular, less than 40% of the patients performed a HBPM

at the same hour, used a chair or bed saddle to support their back during HBPM, repeated the procedure after some minutes, and only half rested for ≥5 minutes before the measurement.

Previous findings were slightly more negative: the only 3 recent Danish surveys that were specifically focused on this topic reported an even lower quality of HBPM: none of the hypertensive participants and pregnant women followed all recommended practices [24], and less than 10% adhered to the required 5-minutes rest time before taking the first measurement [33,34]. Notably, in a previous survey with similar methodology, we found that the overall compliance to guidelines of the BP measurement made by health professionals was substantially lower than HBPM (≥10 recommendations were followed in 33.4% vs 52.8% of the measurements) [20]. Although this is just an indirect comparison, a similar superiority of HBPM over OBPM was reported by most randomized head-to-head comparisons [6,15,38].

The most likely explanation of such a low adherence to some of the recommended practices for HBPM is a scarce training received by the patients [39]. In 2010, a Canadian study reported that less than one third of the patients routinely using HBPM were given specific training on proper measurement techniques, and having received instructions from a healthcare professional was the strongest factor associated with a correct HBPM [40]. Our survey confirms such findings: less than 40% of the participants received some form of training by a health professional, and when patients were instructed the quality of HBPM significantly improved. Importantly, even the patients who read the instructions alone showed a significantly higher adherence than those who received no instructions at all, reinforcing the pivotal importance of an accurate patients' training.

Interestingly, the impact of the instructions on the patients seemed to vary depending on who gave the information: the probability of a higher quality HBPM was significantly higher when doctors or pharmacists provided the instructions; conversely, no improvement was observed when instructions were given by nurses. The latter finding on nurse role is novel and should be considered preliminary. If confirmed, however, it would deserve attention, suggesting either that the quality/quantity of the instructions provided by the nurses are suboptimal, or patients pay less attention to nurses' than doctors' advices, or both.

Such a suboptimal communication between health professionals and patients might be among the reasons for the surprisingly low percentage of subjects declaring they have received some form of training. Given

that current guidelines recommend an accurate training as an essential prerequisite for high-quality HBPM [6,10,28], it could be hypothesized that some of these patients actually received instructions, but they did not pay enough attention to them. Whether such a lack of training was due to poor communication or scarce adherence to guidelines, more attention must be paid on this issue.

Given that the quality of HBPM is influenced by the accuracy and completeness of the instructions provided, efforts should be made to raise awareness among health professionals on the importance of a correct patient's training, with a special emphasis on the recommendations that are less frequently followed and are more important for a reliable measurement. First and foremost, patients should be informed on the importance of performing the measurement more than once, given that recent studies observed a difference in systolic BP of ≥10 mmHg across temporarily close measurements in 30% of patients [41], and a 40% probability of misdiagnosis with a single measurement [42]. Second, operators should educate patients to measure their BP always at the same time, to avoid the misdiagnosis due to the well-known circadian variations of BP [43], which are even more pronounced among hypertensive patients [44]. Finally, patients should be made aware of the risk of overestimating their BP up to 10 mmHg when BP is measured without resting before the procedure [45].

This study has some limitations that must be considered. First, because of the cross-sectional design of the survey, we could not determine causal relationships but only associations in the analysis of the predictors of HBPM quality. Second, although our sample consisted of patients from three large public reference hospitals, we were not able to enroll patients from private clinics, and the sample was not derived using a randomized multistage sampling technique. Thus, the sample cannot be considered representative of the overall population of Italian hypertensive patients. Third, despite the multivariate analysis accounting for the cluster effect of hospital, we only considered a limited number of selected predictors of quality, and several others including the duration of HBPM might be present. Fourth, despite nurses were recommended to be as unobtrusive as possible while observing patients during self-measurement, it is likely that some participants changed their behavior, measuring their BP with more accuracy than at home. Thus, the overall level of HBPM quality has probably been overestimated.

In conclusion, in this sample of hypertensive patients the accuracy of HBPM needs to be improved: several of the recommended procedures were followed by most patients, but the level of adherence to

other important recommendations was unacceptably low. HBPM quality significantly improved when doctors or pharmacists provided instructions to patients, but most patients received no instructions by health operators. More efforts should be devoted to provide an accurate patients' training on HBPM procedures, with a particular attention to the recommendations that are less frequently followed.

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**Table 1**. Overall characteristics of the sample and of blood pressure (BP) self-measurement (n=725).

| Variables | **Overall sample** |
|---|---|
| Male gender, % | 49.5 |
| Mean age in years (SD) | 52.2 (14.4) |
| Married, % | 74.4 |
| *Living status, %* | |
| - Alone | 13.8 |
| - In a family | 85.1 |
| - With a caregiver | 1.1 |
| *Educational degree, %* | |
| - None / Elementary | 21.9 |
| - Middle / High school | 60.0 |
| - Bachelor / Higher | 18.1 |
| Mean systolic blood pressure in mmHg (SD) * | 139.0 (14.5) |
| Mean diastolic blood pressure in mmHg (SD) * | 78.0 (7.9) |
| Mean duration of hypertensive treatment in years (SD) | 11.3 (8.1) |
| *Anti-hypertensive therapy* | |
| - ACE Inhibitors or Angiotensin blockers, % | 45.9 |
| - Beta-blockers, % | 42.3 |
| - Calcium Channel Blockers, % | 41.0 |
| - Diuretics, % | 30.8 |
| - Alpha-blockers, % | 9.0 |
| - Mean number of drugs (SD) | 1.7 (0.7) |
| *Cardiovascular risk factors, %* | |
| - Current smoking | 7.6 |
| - Former smoking | 16.3 |
| - Diabetes | 12.7 |
| - Dyslipidemia | 29.4 |
| *Center, %* | |
| - Chieti-Pescara | 28.6 |
| - Ascoli Piceno | 57.2 |
| - Ancona | 14.2 |
| *BP self-measurement* | |

| | |
|---|---|
| *Instructions, written or verbal, on the correct use of BP device and the measurement procedure* | |
| - I received no instructions at all | 28.8 |
| - I read the instructions by myself | 25.0 |
| - I received instructions by friends | 6.4 |
| - I received instructions by a pharmacist | 5.0 |
| - I received instructions by a nurse | 10.8 |
| - I received instructions by a doctor | 24.0 |
| | |
| *How many BP measurements do you routinely perform?* | |
| - Occasionally, I do not follow a fixed schedule | 63.1 |
| - About 1 per week | 15.3 |
| - About 2 per week | 7.9 |
| - About 1 per day | 6.9 |
| - About 2 per day or more | 6.8 |
| | |
| *Type of device to measure BP, %* | |
| - Mercurial | 12.1 |
| - Aneroid | 0.3 |
| - Electronic, automatic | 50.8 |
| - Electronic, semi-automatic | 24.7 |
| - Electronic, manual | 5.9 |
| - Electronic, wrist | 6.2 |

* Measured by a nurse after the assessment.

**Table 2**. Adherence to guidelines for the self-measurement of blood pressure (BP) in the sample (n=725).

| **Items *** | **Yes, %** | **(95% CI)** |
|---|---|---|
| 1. Do you always measure BP at the same hour (i.e. always fasting in the morning or after eating in the evening)? * | 32.4 | (28.9-35.8) |
| 1b. If not, at what hour do you measure BP more frequently? * | | |
| - Before breakfast | 13.6 | (10.6-17.1) |
| - After breakfast | 30.1 | (25.9-34.6) |
| - Before lunch | 22.6 | (18.9-26.8) |
| - After lunch | 17.8 | (14.4-21.6) |
| - Before dinner | 11.9 | (9.0-15.2) |
| - After dinner | 4.0 | (2.4-6.2) |
| 2. Do you always measure BP using the same arm? * | 71.4 | (68.1-74.7) |
| 3. Do you always measure BP in the same body position (i.e. always sitting or lying)? * | 94.1 | (92.3-95.8) |
| 3b. If so, in which body position do you usually measure BP? * | | |
| - Sitting on a chair | 87.1 | (84.3-89.5) |
| - Sitting on the bed | 5.4 | (3.8-7.4) |
| - Lying | 6.7 | (5.0-8.9) |
| - Standing up | 0.7 | (0.2-1.7) |
| 4. Do you repeat the measurement after some minutes (then take the mean of the 2 measurements)? | 36.8 | (33.3-40.3) |
| 5. Do you keep a diary of BP measurements? * | 27.4 | (24.1-30.6) |
| 6. Did the patient choose the cuff on the basis of his arm circumference? | 77.6 | (74.6-80.7) |
| 7. Did the patient put the cuff properly? | 62.8 | (59.2-66.3) |
| 8. Before BP measurement, did the patient rest for at least 5 minutes? | 49.7 | (46.0-53.3) |
| 9. During BP measurement, was the room calm, with low noise, and no distractions (people talking, radio/television on, etc.)? | 71.6 | (68.3-74.9) |
| 10. During BP measurement, was the patient silent? | 63.7 | (60.2-67.2) |
| 11. During BP measurement, did the patient keep his legs uncrossed? | 90.1 | (87.9-92.3) |
| 12. During BP measurement, was the patient's back supported by a chair or bed saddle? | 34.3 | (30.9-37.8) |
| 13. During BP measurement, was the patient's arm supported (i.e. on a table if he was sitting, or on the bed if outstretched)? | 85.4 | (82.8-88.0) |
| 14. During BP measurement, was patient's arm positioned at the same height of his heart? | 78.8 | (75.8-81.7) |
| 15. During BP measurement, was the point where the bladder arm was located uncovered? | 65.2 | (61.8-68.7) |
| *Overall pattern* | | |
| Eight or more positive answers to the above questions ** | 80.3 | (77.4-83.2) |
| Ten or more positive answers to the above questions ** | 52.8 | (49.2-56.5) |
| Twelve or more positive answers to the above questions ** | 17.0 | (14.2-19.7) |
| All (n=15) positive answers to the above questions ** | 1.0 | (0.3-1.7) |

* Directly reported by the patients. ** Except questions 1b and 3b.

**Table 3**. Random-effect linear regression predicting higher quality blood-pressure (BP) self-measurement.

| Variables | Higher quality BP self-measurement | | |
|---|---|---|---|
| | Crude Coefficient (95% CI) | Adjusted Coefficient (95% CI) [a] | p [a] |
| Male gender | 0.19 (-0.14; 0.52) | 0.23 (-0.09; 0.55) | 0.17 |
| Married | 0.38 (0.00; 0.75) | 0.27 (-0.22; 0.75) | 0.2 |
| Age, 1-year increase | 0.02 (0.00; 0.03) | 0.01 (0.00; 0.02) | 0.15 |
| Living in a family or with a caregiver | 0.09 (-0.39; 0.57) | -0.03 (-0.57; 0.51) | 0.9 |
| Current cigarette smoking | 0.82 (-0.76; 2.40) | 0.92 (-0.95; 2.74) | 0.3 |
| Diabetes | -0.59 (-1.85; 0.68) | -0.77 (-2.10; 0.56) | 0.3 |
| Dyslipidemia | 0.17 (-0.69; 1.04) | 0.13 (-0.81; 1.07) | 0.8 |
| *Educational degree* | | | |
| - None / Elementary | 1 | 1 | -- |
| - Middle / High school | -0.41 (-0.75; -0.08) | -0.06 (-0.51; 0.38) | 0.7 |
| - Bachelor / Higher | 0.50 (0.08; 0.93) | 0.55 (-0.06; 1.16) | 0.08 |
| Systolic blood pressure, 1 mmHg increase | 0.01 (-0.02; 0.04) | 0.01 (-0.02; 0.04) | 0.4 |
| Years of hypertension | 0.03 (-0.03; -0.08) | 0.02 (-0.05; 0.08) | 0.6 |
| *Hypertension treatment* | | | |
| - ACE inhibitors | 0.97 (-0.24; 2.17) | 0.93 (-0.35; 2.22) | 0.15 |
| - Beta-blockers | -0.45 (-1.31; 0.41) | -0.43 (-1.33; 0.47) | 0.3 |
| - Calcium channel blockers | 0.03 (-0.84; 0.90) | 0.06 (-0.89; 1.01) | 0.9 |
| - Diuretics | 0.36 (-0.57; 1.29) | 0.25 (-0.79; 1.30) | 0.6 |
| - Alpha-blockers | -0.86 (-2.34; 0.62) | -0.81 (-2.39; 0.76) | 0.3 |
| - Number of drugs, 1 unit increase | 0.02 (-0.41; 0.45) | 0.01 (-0.45; 0.47) | 0.9 |
| *Instructions on the correct use of BP device* | | | |
| - I received no instructions at all | 1 | 1 | -- |
| - I read the instructions by myself | 0.13 (-0.25; 0.51) | 0.68 (0.24; 1.13) | 0.003 |
| - I received instructions by friends | -0.09 (-0.77; 0.59) | 0.53 (-0.19; 1.25) | 0.15 |
| - I received instructions by a pharmacist | 1.20 (0.45; 1.95) | 1.67 (0.88; 2.47) | <0.001 |
| - I received instructions by a nurse | -0.13 (-0.66; 0.40) | 0.48 (-0.11; 1.07) | 0.11 |
| - I received instructions by a doctor | 0.70 (0.32; 1.08) | 1.09 (0.64; 1.54) | <0.001 |

CI, Confidence Interval. [a] Random-effect linear regression model, using center as the cluster unit.

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