

Research Letter

Measuring accuracy of sphygmomanometers in the medical practices of Swiss primary care physicians

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KEY MESSAGE:

- In a sample of Swiss primary care practices 81.4% of upper arm and wrist sphygmomanometers measured blood pressure within a tolerance of ± 3 mmHg despite low adherence to the advocated maintenance interval of two years.
- The number of devices outside the measurement tolerance increased significantly two years after the last maintenance.

ABSTRACT

Objective: Arterial hypertension has a high prevalence in most countries. Blood pressure measurements are performed frequently by primary care physicians. Recommendations from different societies emphasise the importance of measuring blood pressure with well maintained and calibrated instruments only. Since appropriate quality control measures are lacking the following survey was conducted in the medical practices of Swiss primary care physicians.

Methods: This is a cross-sectional survey with Swiss primary care physicians. Nine hundred and seventy-five sphygmomanometers used in the daily practice of medicine were compared and calibrated against a certified calibrator. The magnitude of the measuring error before and after calibration was determined.

Results: The proportion of the instruments that measured within the required tolerance of ± 3 mmHg over all measuring ranges was 81.4%. The average maintenance time was 5.6 years (± 3.8), and 97% ($n = 353$) of these instruments had not been maintained for two years (i.e. the recommended maintenance interval) or more. Two years after maintenance the number of devices with measurement errors of more than ± 3 mmHg increased significantly.

Conclusion: In Swiss primary care practices, the majority of upper arm and wrist sphygmomanometers measured blood pressure within a tolerance of ± 3 mmHg despite low adherence to the recommended maintenance interval. Two years after maintenance the number of sphygmomanometers with measurement errors increased significantly.

Keywords: blood pressure measurement, sphygmomanometer, measuring accuracy, calibration

INTRODUCTION

Hypertension has a high prevalence in most countries. It is usually diagnosed by primary care physicians, for whom blood pressure (BP) measurement is daily routine. The Swiss Society of Hypertension (SSH) has issued detailed recommendations for the correct measurement of BP (1,2), which also emphasise the importance of using well maintained and calibrated measuring instruments. Aneroid measuring instruments are granted an error range of ± 3 mmHg when compared to mercury-containing instruments (3). However, an evaluation study

yielded that 58% of the tested aneroid measuring instruments exhibited errors exceeding ± 4 mmHg, 44% of these instruments even showed imprecisions of ± 7 mmHg or more (4). Although systematic measuring errors should be avoided by regular recalibration, another investigation indicated that British practices had no agreements on a regular maintenance and recalibration of their measuring instruments (5).

The primary objective of this survey was to analyse measuring accuracy and defects of sphygmomanometers (SPM) used in Swiss medical practices in order to make

proposals for future quality control of BP measurement devices.

MATERIAL AND METHODS

Procedure

This cross-sectional survey was conducted in medical practices of Swiss primary care physicians. In total 6857 primary care physicians were asked to send their daily used SPM to a certified weight and measurement inspection site (Dabamed, Uster, Switzerland) for calibration and maintenance. Four hundred and nineteen (6.1%) responded to the call.

Checking the sphygmomanometers

The submitted SPM were tested for measuring accuracy by using a Thommen calibrator (type EC 300.001.A). Each of the submitted instruments was subjected to a seal-tightness test to determine their fundamental functionality. SPM (in parallel to the reference system) were exposed to test pressures of 300 mmHg; 250 mmHg; 200 mmHg; 150 mmHg; 100 mmHg; and 50 mmHg, while the value displayed on the instrument (i.e. the actual value) was documented. After replacing their defective parts (cuffs, balloons, pumps, measuring mechanisms, glass, electronic components), the instruments were checked again with the reference system. Instruments with a measuring error exceeding ± 3 mmHg were identified as being inaccurate (6). The instruments were then adjusted to a measuring accuracy of ± 0 mmHg by a calibrator with a known measuring uncertainty of ± 0.7 mmHg (6). Finally, a measurement on a test subject (left arm) was performed according to the guidelines of the SSH (1).

Statistical analysis

Measurements were documented prior to and after adjustment and subsequently analysed using SPSS 13.01 (SPSS, Inc., Chicago, IL, USA). Relationships between dichotomous variables were interpreted with the χ^2 test (Pearson). The continuous variables of age were compared using *t*-tests for independent samples, those of the pressure measurements were subjected to a non-parametric investigation with the Mann-Whitney test. Relationships between two continuous variables were depicted with the Pearson correlation coefficient. A *P*-value < 0.05 was considered as significant.

RESULTS

Included physicians

The 419 (6.1%) doctors participating in this study did not differ significantly from the total of 6857 (100%) Swiss

primary care physicians with regards to age, years since graduation and years of practicing. Doctors practicing in towns with at least 10000 inhabitants were slightly under-represented (41.1% compared with 49.9% of the whole sample, $\chi^2 = 13.9$; $P < 0.001$). German speaking doctors were slightly over-represented (86.0% compared with 72.2% of the whole sample, $\chi^2 = 38.7$; $P < 0.001$). Male physicians were more likely to participate (88.4% compared to 72.2% of the whole sample, ($\chi^2 = 53.3$; $P < 0.001$), while specialization (general medicine, internal medicine) or additional work in a hospital did not influence the participation rate.

Included instruments

A total of 975 SPM from 419 primary care physicians were analysed within this survey, 61 instruments (6.3%) were excluded up-front due to a complete lack of functionality. Therefore, 914 (100%) functional instruments were revised, 877 (96.0%) out of them were successfully recalibrated. Thirty-seven (4.0%) instruments could not be recalibrated, and thus did not meet the requirements for further use. While 10.5% ($n = 96$) of the included instruments were wrist SPM, 87.3% ($n = 798$) were upper arm instruments. In 60.1% ($n = 549$) of the tested instruments, their age was known. The mean age of the instruments was 7.8 years (± 6.9).

Maintenance and calibration

In only 39.8% ($n = 364$) of the devices the physicians were able to remember the date of the last calibration. While the average maintenance time was 5.57 years (± 3.8), 97.0% ($n = 353$) of these instruments had not been maintained for two years or more.

Measuring accuracy of the sphygmomanometers

The overall absolute measuring error was 2.14 mmHg (± 1.74). The measured deviations of the instruments with regards to all six test pressures were similar without significant differences between upper arm and wrist SPM ($\chi^2 = 0.72$, $P = 395$). The proportion of instruments showing a measuring accuracy that did not require any adjustment according to the rules of Swiss Calibration Service (6) was 81.4%. Of the 170 instruments that fell outside of the measuring tolerance of ± 3 mmHg (18.6%; 146 upper arm, 21 wrist, 3 unknown type), 102 (60.0%) and 68 (40.0%) demonstrated falsely high and falsely low measurements respectively. In 38 instruments the deviation exceeded + 5 mmHg, in 20 instruments it was more than -5 mmHg. The time since the last calibration correlated positively, although modestly, with the absolute average measuring error (Pearson's $r = 0.118$; $P = 0.024$). Two years after the last calibration measurement errors increased significantly ($P < 0.001$).

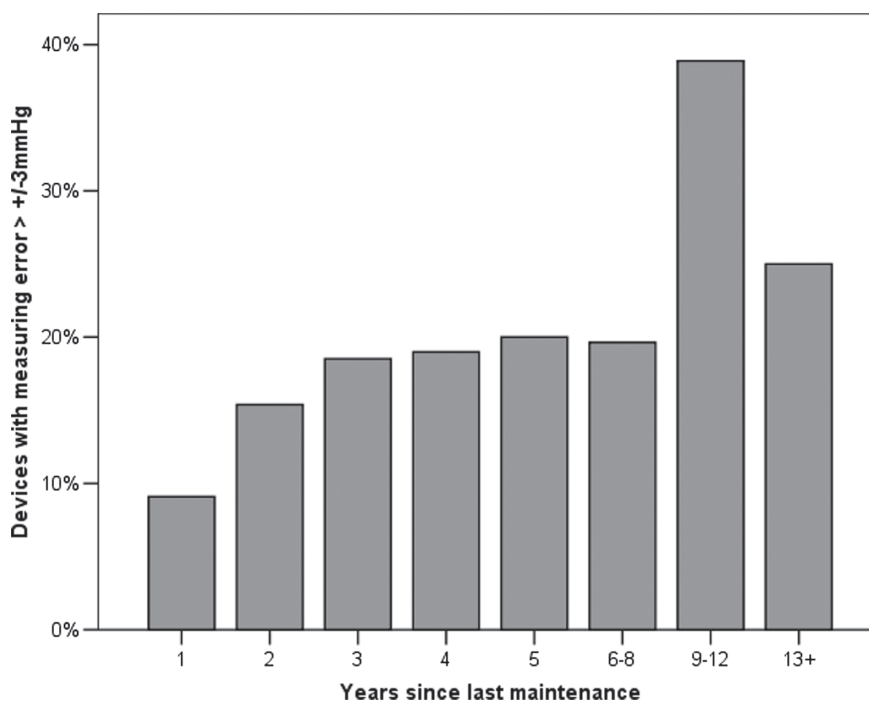


Figure 1. Time since last maintenance and frequency of measuring errors. The percentage of measuring errors (more than ± 3 mmHg) was significantly higher in devices with maintenance periods of two years or more ($P < 0.001$).

Pearson's correlation coefficient between the age of the instrument and the magnitude of the absolute mean measuring error was $r = 0.118$ ($P = 0.006$).

Repairs

Among the 914 SPM, 505 (55.3%) had to be repaired. The most frequent repairs concerned defective valves (33.8%); seals (18.2%); cuffs (11.7%); rubber balls (10.2%); mercury (content or the position of its column 5.1%); measuring movements (3.0%); electronic components (2.5%); glass rings (2.4%); and batteries (2.3%). Although not all defects influenced measuring accuracy, they were a potential cause for measuring errors. While 24.8% of the repaired devices had exceeded the tolerance of ± 3 mmHg, only 11% of the non-repaired ones were outside this limit ($P < 0.0001$). Only the following defects had a significant influence on the number of devices outside the measuring tolerance: valves (27.2% versus 14.2%, $P < 0.0001$), mercury (34.0% versus 17.8%, $P < 0.0052$), measuring movements (88.9% versus 16.5%, $P < 0.0001$), and glass rings (54.5% versus 17.7%, $P < 0.0001$).

DISCUSSION

Main findings

This is the first large survey on the measuring accuracy of SPM in Switzerland. The majority (81.4%) of the 914 tested instruments exhibited a measuring error that fell within the presently recommended tolerance of ± 3 mmHg. The average maintenance interval was 5.6 years,

and 97.0% of the instruments had not been maintained for two years or more. Two years after the last maintenance the number of devices with measurement errors of more than ± 3 mmHg increased significantly.

Consequences of measuring error

A recently conducted study in the UK yielded similar findings indicating measuring accuracy of 86% (7). Even though our results are comparable with other European countries, it can be argued that 18.6% (11.4% falsely positive, 7.4% falsely negative) inaccurately measuring devices are not acceptable for clinical practice. Although misdiagnosis of hypertension due to white coat effect is important, measurement errors are clinically relevant too, because they may lead to unnecessary, excessive therapy or under-treatment. Hence, Turner et al. reported that overestimation of systolic blood pressure by 3 and 5 mmHg increases the number of patients classified as hypertensive by 24% and 43% respectively (8). Underestimation of systolic BP by 3 and 5 mmHg causes 19% and 30% of patients with systolic hypertension to be missed (8). Elevation of BP by 2 mmHg may increase the risk of stroke by 7% (9).

Maintenance interval

Our data show the influence of recalibration intervals and age of the devices on their accuracy. Two years after maintenance the number of SPM with measurement errors increased significantly (Figure 1). Although there is no requirement for regular maintenance of SPM at

specific intervals, Swiss calibration service recommends every two years (6). In our survey the average calibration interval was 5.57 years. Our findings are in line with the poor awareness for regular checks of devices indicated by a study where 40% of the family doctors could not remember the last calibration date of their SPM (10). Similarly, 23% of interviewed English family doctors never performed maintenance or did so at an interval of > 6 years (10). Our data support the recommended maintenance and calibration intervals of two years, which has been determined by technical considerations (11).

Types of devices

We could not detect significant differences in measurement accuracy between wrist and upper arm measurement instruments, which is controversial to a Turkish study showing that inaccuracies of wrist devices are more frequent (12). Since our investigation exclusively focused on technical systematic errors, we have no data on the influence of the position of the device on the measurement.

Limitations

As participation in the survey and revision of the instruments were free of charge, doctors may have included their older device too, although they were asked to send in the devices used in their daily practice. Only 6.1% of the Swiss primary care physicians participated in this study. However, they were representative concerning age, years since graduation, years of practicing and specialisation. Although male doctors, German speaking physicians and those of rural areas were slightly over-represented, this did not influence the accuracy of the devices. Therefore, we consider the results of this sample as a valuable indicator for the whole population of Swiss primary care physicians.

The data of this study suggest a maximum maintenance interval of two years. However, this is based on a small statistical base.

Conclusion

Measuring deviations of more than ± 3 mmHg occur in nearly one fifth of the sphygmomanometers; they are clinically relevant, as they can lead to over- or under-treatment of hypertension. Maintenance intervals should not exceed two years.

ACKNOWLEDGEMENTS

Novartis Pharma Switzerland supported the study. It made available physicians' addresses for recruiting participants and funded the study by an unrestricted grant.

Declaration of interest: Hans-Hendrik Schäfer was employed by Novartis as a medical advisor from 2008–2010. The authors do not report any conflict of interest. The authors alone are responsible for the content and writing of the paper.

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