The role of the measurement uncertainty and error in the blood pressure measurement

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Abstract. The blood pressure measurement is a routinely procedure conducted in primary cares, health cares, pharmacies or even at home, by physicians in order to diagnosis hypertension, as well as by the users in order to administer medication. The sphygmomanometer is the instrument used to the procedure, however the indication of the blood pressure displayed is not always the true value of the measurement. Deviations due to measurement errors and uncertainties, an intrinsic component of all measuring devices, affect the indication, and consequently might affect the patient diagnosis. For example, a health patient can be diagnosed as hypertensive, demanding an unnecessary treatment. Then, the present study aims to investigate the impact of the measurement error and the uncertainty in misdiagnosis for hypertension. We applied a sphygmomanometer with well-known measurement error and uncertainty to a sample of patients with well-known blood pressure in order to identify how these parameters affect the result according to the instrument indication. The results show a misdiagnosis of 3.98%, for the diastolic and 4.29% for the systolic pressure, to the sphygmomanometer used in the simulations. The results show the importance of considering the metrological parameters for the diagnosis.

1. Introduction

Blood pressure measurement is a simple procedure conduct in primary cares, home care, pharmacies, hospital and it is widely used to diagnose hypertension. The sphygmomanometer is the measuring instrument used for the procedure, and its metrological requirements are under the control of legal metrology.

Maximum permissible errors (MPE), as well as several other technical requirements are well defined in the international recommendations issued by the International Organization of Legal Metrology – OIML [1]. Although several studies have already investigated the accuracy of sphygmomanometers [2-5], the literature of the measurement errors (ME), which represent a measured quantity minus a reference value [6], and how they impact the medical diagnosis in hypertension is sparse [7]. A study demonstrated that a systematic error is an important component for diagnosing showing that, a deviation of +3 mmHg increases in 68% the false positives of patients with blood pressure superior to 90 mmHg, and a deviation of -3 mmHg, 44% of hypertension patients would not be diagnosed [8].

The measurement uncertainty (MU), representing the dispersion of the quantity values attributed to the measurand [6], is an important information regarding any instrument, and when added to the ME provides the entire information regarding the measurement, representing a true value, i.e. an interval
where the true measurement lies despite the instrument indication. Consequently, MU is an important component that shall be considered in the international recommendation regarding the sphygmomanometer [9].

The present study aims to show how the MU affects the diagnosis of hypertension. We used, in order to measure the blood pressure, a calibrated sphygmomanometer with well-known ME and MU and simulated how those deviations affect the true value according to the instrument indication. We also used a sample of patients from the medical literature with well-known blood pressure behaviour.

2. Methodology

The simulation were conducted using a sample of patients comprising 423 individuals from the medical literature [10], which parameters of blood pressure follow a Normal distribution, as shown in table 1.

| Blood pressure | Mean (mmHg) | Standard Deviation (mmHg) |
|----------------|-------------|---------------------------|
| Systolic       | 128.5       | 23.0                      |
| Diastolic      | 79.5        | 12.5                      |

Additionally, a digital sphygmomanometer parameters regarding ME and MU was used as a reference to carry out the simulations. The device was calibrated in an accredited laboratory in Mar/2017 and its calibration parameters are given in table 2.

| Standard | Indication | Measurement Error (mmHg) | Measurement Uncertainty (± mmHg) |
|----------|------------|--------------------------|----------------------------------|
| 40       | 39         | -1                       | 1                                |
| 80       | 79         | -1                       | 1                                |
| 120      | 118        | -2                       | 1                                |
| 160      | 158        | -2                       | 1                                |

For a blood pressure procedure, where the sphygmomanometer indicates $I$, the measurement true value is represented by the indication $I$ plus the correction $\bar{x}$, (according to table 2, the correction is positive) and the measurement uncertainty $U$, as shown in (1). Based on the parameters of the sphygmomanometer used (negative measurement errors), we have a positive correction. Consequently, figure 1 shows the misdiagnosis due to negative measurement errors (positive corrections).

$$\text{true value} = I + (\bar{x} \pm U)$$

In order to determine the misdiagnosis, according to figure 1, the number of hypertensive patients that would not be diagnosed is shown is given by (2).

$$y = \int_{P_H}^{+U} f(x) \, dx = \int_{P_H}^{+U} \frac{1}{\sqrt{2\pi\sigma^2}} e^{-\frac{1}{2}(x-\mu)^2} \, dx$$

Where $f(x)$ is represented by the Normal distribution with mean $= \mu$ and standard deviation $= \sigma$. The $P_H$ threshold pressure for hypertension diagnosis is defined as $P_H = 90$ (diastolic) and 140 mmHg (systolic) [11]. The $I$ values around $P_H$ were considered to the simulation, as they represent the affected region for a correct diagnosis, based on the measurement errors of the simulated sphygmomanometer. All the simulation were conducted using the software Scilab 5.5.2.
3. Results

In order to obtain the misdiagnosis caused by a calibrated sphygmomanometer with ell-known parameters, according to table 2, we computed the percentage of misdiagnosis according to the indication of the instrument, based on the sample with well-known BP. The results for both DP and SP are displayed in figure 2 and 3, respectively.

According to figures 2 and 3, it is possible to conclude that the probability of misdiagnosis increases toward the $P_H$ value, for both DP and SP. In the boundary regions, for an instrument indicating 89.9 mmHg, there is a misdiagnosis 3.98%, for DP. Similarly, to an indication of 139.9 mmHg, the misdiagnosis considering the SP is of 4.29%. These boundary indications would represent approximately 17 (DP) and 18 (SP) normal patients that would be diagnosed as hypertensive, consequently demanding unnecessary treatment, based on the sample.

For indications below 88 mmHg and 137 mmHg, misdiagnosis would not be caused by the MU and the ME once these values did not overpass the $P_H$ values, according to the parameter of the sphygmomanometer tested. However, for greater ME and MU, the misdiagnosis would consequently increase, causing a greater impact, causing incorrect treatments.
4. Conclusion
The blood pressure measurement is a vital procedure used to diagnose hypertension. Additionally, the sphygmomanometer is also commonly used by patients at home in order to identify when to administer a medication. Furthermore, the deviations in the measurement caused by both measurement error and measurement uncertainties impact the diagnosis, causing for example, unnecessary treatments to normal patients. The unnecessary treatments also affect the economics aspect, where unnecessary expenditures would be demanded.

The present study showed how the measurement uncertainty, as part of the measurement error, impacts the diagnosis, causing misdiagnosis affecting the patient treatment. Moreover, the closer the instrument indication is to the threshold to hypertension, the greater are the incorrect diagnosis, due to the area covered by true value.

The improvements in the field that support the enhancement of metrological features, such as the repetitiveness of the sphygmomanometers, as well as the incorporation of the MU as a requirement in the international recommendations, are some initiatives that should decrease the misdiagnosis due to measurement deviations. Finally, the medical community should also be aware of the impacts of the metrological characteristics of the clinical instrumentation, in order to prevent mistreatments.

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