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Logistic ordinal regression for the calibration of oscillometric blood pressure monitors

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ABSTRACT

Oscillometric blood pressure (BP) monitors are omnipresent and used on a daily basis for personalized healthcare. Nevertheless, physicians generally approach these devices cautiously since the mercury Korotkoff sphygmomanometer remains the golden standard. Various reasons explain the hesitating attitude of the medical world towards automated BP monitors: (i) its principle is based on the pressure pulsations arriving at the cuff by the cardiac cycle instead of an audio wave used by physicians triggered by the turbulences in the artery, (ii) the actual computation of the systolic and diastolic BP from the measured oscillometry is manufacturer dependent and not based on general scientific principles, (iii) the quality of the oscillometric monitors is labeled by a trial such that the devices correspond well to the Korotkoff method for the average healthy patient but deviates for patients suffering from hypo- or hypertension. In this paper, we develop a statistical learning technique to calibrate and correct an oscillometric monitor such that the device better corresponds to the Korotkoff method regardless of the health status of the patient. The technique is based on logistic regression which allows correcting and eliminating systematic errors caused by patients suffering from hyper -or hypotension. No user interaction is required since the technique is able to train and validate the calibration procedure in an unsupervised way. In our case study, the systematic error is reduced by nearly 50% corresponding to the performance specifications of the device.

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1. Introduction

Personalized healthcare and home health monitoring is a booming business. This is due to aging and the advanced technologies in telecommunication applications. From a technological perspective, one needs to ensure that we do not clear the path for a wild growth of medical monitors such that medical devices are based on scientific principles ensuring quality. The safeguard should consist of reducing the discrepancy between (low cost) home monitors and more expensive and specialized clinical devices. Nevertheless, the quality difference between the clincal device and the home monitoring system is apparent due to cost, space, and layman use.

In an effort to eliminate the gap between the Korotkoff method applied in the sphygmomanometer [1] and the oscillometric devices a calibration procedure needs to be established [2,3]. The calibration method eliminates the systematic error by comparison with the Korotkoff results denoted as the golden standard. A few constraints to establish this procedure are: (i) the patient needs to be able to perform the calibration at home, (ii) additional hardware should be avoided, (iii) The patented algorithm should remain unchanged. The calibration problem is two-fold: The systematic error needs to be detected and the systematic error needs to be corrected. Since 1999, test simulators for the calibration of oscillometric devices have been introduced [4–6]. Such simulators apply test signals to the oscillometric device for testing the accuracy of the measurement. Either these simulators require additional hardware or they apply a database of oscillometric signals to correct the algorithm computing the BP values [7]. Once a systematic error is detected, post-processing should account for this discrepancy without changing the patented algorithm. Most research on oscillometric blood pressure signals is focused on either understanding the fundamental signal properties [8–10], blood flow dynamics in the presence of delating cuff [11,12], filtering techniques [13] and signal feature detection with various methods [14].

The number of published results regarding the (post) correction of automatic blood pressure monitors is significantely less abundant. For instance a denoising approach to eliminate confounding

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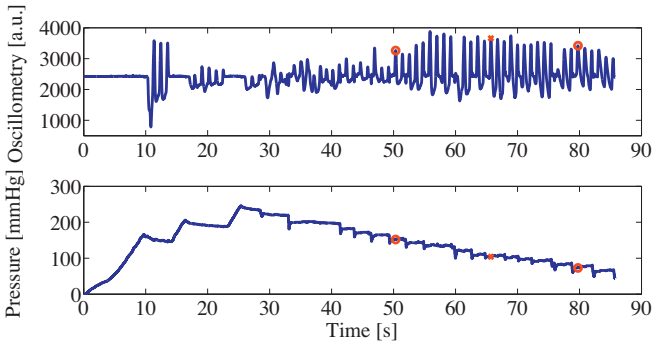

Fig. 1. Oscillometric BP determination: oscillometric signal (top) – cuff pressure (bottom). BP values: systolic (left circle), MAP (cross marker), diastolic (right circle).

and movement artifacts was studied in [15]. Temporal variability was modeled and suppressed in [16,17]. To obtain more accurate readings the blood pressure variability was measured and taken into account in [18]. In [19,20] we tried to correct the oscillometric monitors for patients with an extremely high or low blood pressure by taking into account a dynamic blood flow model.

In this paper, we want to study a statistical technique which can be used together with a test simulator for oscillometric devices. Test signals are fed to the oscillometric devices to quantify the discrepancy between the Korotkoff sphygmomanometer and the automatic oscillometric monitor. Based on the signal characteristics of the measured oscillometric signal and the oscillometric blood pressure readings a logistic regression is applied for the bank of test signals to identify a correction rule for the automatic blood pressure monitor. The actual relationship between the signal features and the Korotkoff blood pressure is highly nonlinear such that only a limited performance can be observed by using a linear regression to map the shape of the oscillometric signal to the blood pressure see [19]. To avoid a crusade for a very complex nonlinear model, we remain in the linear modeling framework. As a result, we can rely on the linear regression framework but not to estimate the correct blood pressure specifically but to estimate the correct range of the blood pressure. This type of linear regression is known as logistic regression.

2. Blood pressure (BP) measurement campaign

2.1. Korotkoff spygmomanometer against the oscillometric monitor

The golden standard for measuring the blood pressure remains the Korotkoff sphygmomanometer. The sphygmomanometer inflates a cuff wrapped around the patient's upper arm until the blood circulation is stopped. A stagewise deflation of the cuff restores the blood flow while slowly opening the artery. Through the stethoscope, the physician listens at the turbulences caused by restoring the blood flow. The sound type of the turbulences undergo five phases known as the Korotkoff sounds [1]. The systolic blood pressure is determined at the start of the first Korotkoff sound whereas the diastolic pressure is defined by the final Korotkoff sound.

The oscillometric monitors also apply a cuff but instead of recording the turbulences in the arteries, the pressure pulsations of the heart arriving at the cuff are measured. The pulsations hold an oscillating nature due to the systolic and diastolic phases of the heart cycle. On top of that the deflation of the cuff acts as an amplitude modulation on the blood pulse oscillations. This amplitude modulated signal is known as the oscillometric signal. The determination of the systolic and diastolic BP from the oscillometric signal is obscure in the sense that a unique algorithm is not available. Indeed, there are two important theoretic schools which conjecture that the BP is a function of the relative height of the oscillometric signal w.r.t. the global maximum (height based school) whereas a second school is in favor of the BP as a function of the points of inflection of the oscillometric signal around the global maximum [21,22]. On top of that, the exact implementation to determine the inflexion points, the exact percentages to pin-point the relative heights w.r.t the global maximum differ from brand to brand due to possible patented software solutions. Once the algorithm computes the necessary points on the oscillometric signal, the time instant is traced back to the cuff pressure which determines the systolic and diastolic pressure (see Fig. 1 as an illustration).

2.2. Measurement set-up

A measurement campaign following the protocols of the British Hypertension Society. In total, the campaign selected 75 patients. The patients were randomized in terms of age, sex, and socio-cultural background. However, half of the patients were selected among patients without cardiovascular issues whereas the other half of the selected patients have records indicating cardiovascular problems.

The used oscillometric measurement device was the Contec PM-50 a blood pressure monitor certified by the FDA. The device is validated for upper arm measurements only. It has a systolic pressure range between 40 and 270 mmHg, a mean arterial pressure (MAP) range between 20 and 235 mmHg and a diastolic pressure range between 10 and 215 mmHg. A continuous monitoring option with a periodic measurement interval of at least 5 min. The pressure is quantized at an accurary of 1 mmHg. The inflation is by means of a forced pump while the deflation is stagewise with steps of 4 mmHg. The FDA reports the device to be accurate with a root-mean-square (RMS) error of 6 mmHg.

2.3. Data: descriptive statistics

An expert physician selected 100 healthy and 100 unhealthy (cardiovascular problems) patients from a pool of patients based on some qualitative parameters to avoid confounding: mixed backgrounds, sex, education, medical history,... From this set of 200 patients a random sampling was performed by the physician to obtain the 75 measured oscillometric signals. The patients were examined by means of the Korotkoff sphygmomanometer following the abovementioned protocols. The blood pressure is partitioned into different groups according to the cardio-vascular risks. We discriminate Hypotension (Systolic < 90, Diastolic < 60), Desired (90 < Systolic < 120, 60 < Diastolic < 80), pre-hypertension (120 < Systolic < 140, 80 < Diastolic < 90), Hypertension stage 1 (140 < Systolic < 160, 90 < Diastolic < 100), Hypertension stage 2 (160 < Systolic < 180, 100 < Diastolic < 110) and crisis (Systolic > 180, Diastolic > 120).

Table 1 shows the Korotkoff readings performed by a certified physician for the different patients in the campaign. The table reveals that for the diastolic pressures slightly <53.3% of the patients reveal pressures beyond the desired range while for the systolic pressures this holds for 75.4% of the patients. Given that oscillometric devices are based on an algorithm computing the blood pressure. This suggests that these algorithms work reasonably for patients in the desired blood pressure range but these devices normalize the estimated blood pressure for hypo- and hypertensive patients towards the desired ranges. As a result, the campaign shows quite some patients outside the desired range which poses a challenge for the oscillometric devices for which a correction of the oscillometric signal may be desired.

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