Statistics on medical devices performance assessment – a case study

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When developing a new medical technology, a crucial step is to prove that the device performs accordingly with the expected. This study shows the statistics implemented to analyse the performance of a device to assess arterial pulse waveform in the carotid artery and other parameters such as Augmentation Index (AIx) and central arterial pressure (CAP). This new device was based on optical fiber technology and was developed as a cost-effective alternative to the electronic state-of-the-art devices usually know as tonometers.

To know if the device could be used as an alternative to regular tonometers, a comparison between it and a state-of-the-art was performed. The literature showed different statistical approaches to investigate agreement between measurements assessed with different techniques. Student t-tests are frequently used to analyse potential significant differences between results or different measuring methods. The used confidence interval is typically 95 %, reflecting a significance level (p-value) of $p<0.05$. As a measure of agreement between techniques, Bland-Altman plotting is applied in the majority of the literature references. As correlation studies, Pearson's (PCC) and Intraclass (ICC) correlations coefficients are frequently calculated, with common confidence intervals of 95 %.

For the performance analysis, the optical fiber device was tested against Complior Analyse®, a recognized state-of-the-art device. Since the measures could not be performed simultaneously, alternated measures of non-invasive carotid arterial pulses were taken. Arterial pulses sequences were measured in 76 patients, a similar number of subjects of other clinical evaluation studies.

The analysis started with the comparison of the arterial pulse waveforms. Each pulse acquired with both techniques was superimposed for all subjects to perform point-by-point ICC. ICC was chosen because it is used to evaluate different techniques outputs to acquire the same variable in the same subject. An ICC between 0.7 and 0.8 was considered to represent a strong agreement between techniques and an ICC higher than 0.8 a very strong agreement. AIx, and cSP were also compared for both techniques. Bland-Altman plots, were applied to these variables and analyse the accuracy of the device measurements. The statistical calculations were made with IBM SPSS Statistics 23.

For the arterial pulses waveforms point-by-point correlation an ICC of 0.96 ± 0.03 was found. As concerns to AIx, an ICC of 0.91 ($p < 0.001$) was obtained. The Bland Altman analysis showed a mean difference of 1.9 ± 12.2 %. Regarding cSP, the Bland-Altman showed a mean pressure difference of 9 ± 5 mmHg, however an ICC of 0.98 ($p < 0.001$) was obtained. The strong correlations between the new device and the reference showed that this probe is accurate in the acquisition of carotid pulse waveforms.