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A new invasive validation method for non-invasive central blood pressure measurement using a suprasystolic sphygmomanometer

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Background: Central blood pressure (cBP) is a better predictor of the damage caused by hypertension in comparison with peripheral blood pressure (pBP). Although challenging to measure, numerous devices are trying to reliably estimate cBP non-invasively. Pulse wave velocity (PWV) is another important independent cardiovascular risk factor.

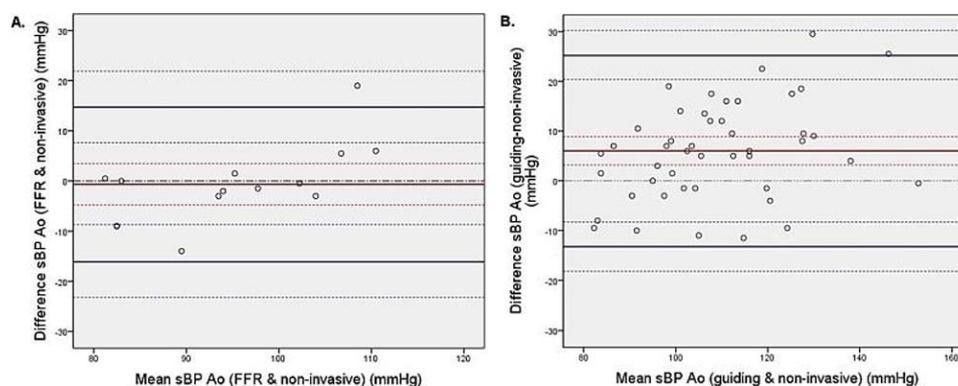
Aim: We sought to deploy a new validation method using a high-fidelity pressure wire as the invasive gold standard measurement for sphygmomanometer devices estimating cBP. Moreover, we invasively calculated the PWV to investigate its relationship to the non-invasively estimated cBP.

Methods: In 50 patients requiring a cardiac catheterization, we measured the blood pressure in the ascending aorta (AAo) with a fluid-filled (FF) guiding catheter (NaCl 0,9%). We compared these values with the results derived simultaneously with a novel sphygmomanometer that estimates cBP from the analysis of brachial artery suprasystolic pressure waves, based on the pressure-wave propagation of a water-hammer acoustic model. This was measured on the left arm with the BP+ device from USCOM Pty Ltd (Sydney, NSW, Australia) while the catheterization was performed via the right radial artery. On 14 of these patients so far, we placed a 0.014" high-fidelity pressure wire in the AAo to measure cBP, when it was clinically indicated to evaluate one or more coronary stenosis by Fractional Flow Reserve (FFR). Ultimately, the wire was pulled back into the humeral artery (HUM). PWV was then calculated from the length of the pullback and the

time delay between AAO and HUM pulses by gating to the R-wave of the ECG for both measurements, using MatLab software.

Results: Bland-Altman analysis of the sphygmomanometrically estimated cBPs and the measured one by a FFR wire (left on figure) demonstrates less scatter than with the FF catheter (right). The mean difference with the sphygmomanometrically derived cBPs was -1.2 ± 4.7 mmHg (CI95%: $-3.8; 1.8$) for the FFR wire and 6.0 ± 9.8 mmHg (CI95%: $3.2; 8.9$) for the FF catheter. Central diastolic and mean BP were both overestimated by the sphygmomanometer, with respectively -7.8 ± 6.8 mmHg (CI95%: $-11.4; -4.2$) and -5.5 ± 6.1 mmHg (CI95%: $-8.6; -2.3$) compared to the FFR wire and -10.3 ± 6.7 mmHg (CI95%: $-12.2; -8.3$) and -5.5 ± 6.5 (CI95%: $-7.3; -3.6$) for the FF catheter. The average PWV was 7.0 ± 1.4 m/s. No significant relationship of PWV and cBP was identified ($p=0.189$). The PWV was 0.8 m/s lower in patients with only one cardiovascular risk factor versus more than one, but without reaching statistical significance.

Conclusions: Using a FFR wire in the AAo as a high-fidelity pressure reference, we demonstrated that cBPs derived from this new sphygmomanometer was accurate, with a non-significant bias (<5 mmHg) and high precision (standard deviation <8 mmHg) as recommended, criteria not met using the FF guiding catheter measurements. PWV measurements were also easily obtained from the FFR wire method.



cBPs measured. A. FFR; B. FluidF vs BP+