Technical Note: 9

Validation and Reproducibility of SphygmoCor Px

SphygmoCor Pulse Wave Analysis uses the principle of applanation tonometry to record a peripheral arterial waveform and applying a generalised transfer function to obtain a derived central aortic waveform.

Validation of generalised transfer function

Early studies analysing the use of a generalised transfer function between the ascending aorta and the upper-limb arteries have shown good consistency between the measured and derived waveforms and values taken from the waveforms pollutant.

The largest and most comprehensive study was performed by Pauca et al. to confirm that the use of a generalised transfer function utilised by Sphygmocor provided substantially equivalent estimate of the ascending aortic systolic, diastolic and pulse pressures under different conditions. The ascending aortic and radial artery pressure waves were recorded simultaneously in 62 anaesthetized patients before initiation of cardiopulmonary bypass, both before and during intravenous infusion of NTG, with fluid filled manometer systems. Estimated waveforms were compared with simultaneously recorded waveforms.

Comparisons were made for systolic, diastolic, mean and pulse pressures of individual paired waveforms and in corresponding ensemble-averaged waveforms over a 10 second period for patients with regular and irregular heart rhythms. Correspondence between pressure values from SphygmoCor derived aortic pressure waveforms and measured aortic waveforms was excellent. (Difference between SphygmoCor derived aortic and measured aortic pressures were as follows: Systolic Pressure 0.0 ± 4.4 mm Hg, Diastolic Pressure 0.6 ± 1.7 mm Hg, Mean Pressure 0.5 ± 2.0, Pulse Pressure 0.7 ± 4.2 mm Hg). Pressure differences remained of the same order during infusion of NTG.

Reproducibility and Repeatability

A number of studies have been performed to assess the reproducibility of performing SphygmoCor Pulse Wave Analysis measurements. A high level of repeatability and reproducibility has been shown during each study and that it can be used on a range of patient groups.

Wilkinson et al. studied the reproducibility of augmentation index (AIX) on 33 subjects (5 controls, 12 diabetics and 16 hypertensives) aged between 24 and 67 years. Two investigators each performed two readings (in random order). The inter-observer difference was 0.23 ± 0.66% and the intra-observer difference was 0.49 ± 0.93%.

Seibenhoeffer et al. assessed 25 healthy patients (15 male) with mean age 33 years. Two investigators each performed one reading immediately consecutively of each other on three separate occasions. The differences between the two investigators for each subject at each sitting were analysed. The inter-observer differences for AIX was 0.4 ± 6.4 %. No significant difference was observed between the readings.

Filpovsky et al. assessed parameters of wave reflection, augmentation pressure (AP) and AIX. Two measurements were taken by each of the two investigators each investigator on a cohort of 88 healthy subjects, aged 19-53 years, on separate visits in random sequence on two separate visits. No significant difference was observed in AIX or AP either within each visit, between the two
visits or between the two investigators, indicating excellent repeatability and intra- and inter-observer reproducibility.

Recently, Savage et al assessed the variability of AIx on a range of healthy, pre-dialysis, dialysis and renal transplant patients (total pool of 188 patients). A single investigator performed 2 measurements on the same day on 188 patients, with an intra-observer difference of 0 ± 4%. For the inter-observer studies, two investigators each performed two measurements on 2 separate occasions, resulting in an inter-observer difference of 0 ± 3% and –1 ± 9% for the short and long term studies, respectively.

References