Reviewer's report

Title: Assessment of central haemodynamics from a brachial cuff - a community based feasibility study

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Reviewer: Chen-Huan Chen

Reviewer's report:

- Major Compulsory Revisions

This paper reports the central and peripheral blood pressures and augmentation parameters from a large convenient and unselected community-based population, using a novel cuff-based blood pressure monitor. The reported age and sex associations with central and peripheral blood pressures were similar to those reported in the literature. It is a well-written article which performs comprehensive analyses on their data collected in a community-based setting to test the “feasibility” of an oscillometric device in producing comprehensive central hemodynamic indices. Although the paper is well-written, however, some major issues relating to the study design and rationale remain to be elucidated.

It is unclear about the question that this study attempted to respond to. If this is a feasibility study, as the author listed in the title, it is hard to understand why a FDA approved portable noninvasive blood pressure monitor would not be feasible in a community-setting? In addition, for a feasibility study, the main focus of this study should be investigating the success rate of executing the exams and the characteristic and reasons of those failure cases, which were not well addressed in the present study. Besides, having taken into consideration of economic factors, the technical feasibility of this new device can therefore be demonstrated.

In viewing this report, it seemed that the main effort of this study was to answer “whether data from a new brachial cuff-based method would mimic data obtained by McEniery”(page 10, 2nd paragraph”. Unfortunately, the use of a convenient unselected study population without sufficient demographic and medication data precludes the comparison with the epidemiological data reported from the literature. “Feasibility” would not be granted by demonstrating the similarity of the study results to the reference literature. The authors may also wish to justify the accuracy of the novel blood pressure monitor by showing it is actually a comparative study with the attempt to produce similar results as those obtained from comparing to the currently accepted gold standard method. However, this accuracy issue can only be addressed if this is the real question that the author tried to address, it would be of utmost important by incorporating to carry out concurrent reference method in the study design. during the measurement, which is not described in the manuscript.

It’s well recognized that a reconstructed aortic pressure waveform loses detailed characteristics that are critical for the identification of the inflection point resulting
from the wave reflections (Circulation 1997;95:1827-36). In this regard, it has been a debatable issue to use reconstructed aortic pressure waveforms to estimate the intensity of wave reflection, e.g., augmentation index and augmentation pressure, which are part of the main focuses in this study. Given the acceptance of generalized transfer function approach for pulse wave analysis, using an oscillometric wave as a surrogate pressure waveform is an alternative but should be considered judiciously. The ARCSolver method, by applying a similar generalized transfer function to the oscillometric pulse wave, has the potential to obtain all central hemodynamic indices from the reconstructed aortic pressure wave. Although it is feasible, it may not be accurate in the estimation for all of these indices. The oscillometric pulse wave tracks brachial pressure waveform reasonably well but lacks sufficient signals in the high frequency components that are critical for accurate identification of the inflection point for the calculation of the wave reflection indices. This viewpoint has been described in author’s discussion as well (page 11, second paragraph). To sum up, despite of its technical easiness, using a surrogate waveform without full message of brachial pressure wave and the transfer function approach which further reduces details on the reconstructed aortic pressure waveforms will inevitably render the parameters obtained by this novel method less valid.

Besides, Aas discussed in the paper on page 11 and 12, “It is important to note, however, that the reference noninvasive methods themselves (e.g. SphygmoCor) display a degree of error when compared to invasive measures and therefore neither method provides a “true” measurement of augmentation index.” This well established concept was also investigated and presented in a previous study (Circulation 1997;95:1827-36). Given acceptance of SphygmoCor as a gold standard to estimate augmentation index, which is apparently not the case, the authors also discussed in their page 11: “However, for measures of augmentation index, the standard deviation between ARCSolver and estimates from the SphygmoCor device was 7.9% for Alx.” Therefore, the limits of agreement of ARCSolver method in the estimation of Alxaugmentation index could reach 31% (=1.96*2*7.9). Obviously, it may not be a clinical acceptable test even the estimates could be produced easily.

- Minor Essential Revisions

Page 4: “Under controlled laboratory settings the device demonstrates realistic and valid estimates of central BP and augmentation index and performance equals that of current reference non-invasive techniques (SphygmoCor) when compared with measures derived invasively.[21,22]”.

The author should consider replacing ref. 22, which is an abstract, with the more appropriate reference as below.


Moreover, in this paper, the author reported the mean difference for estimating central SBP was -3.0 ± 9.5mmHg when comparing the non-invasive estimates to
invasive measured values. The statement of “realistic and valid estimates” should be used cautiously because current proposed validation standards for oscillometric blood pressure monitors, even not appropriate for central BP monitors, request that the mean difference and standard deviation of differences should be less than 5 ± 8 mmHg. In fact, all the central BP estimates by the transfer function approach, even using sphygmoCor, suffered from calibration errors. (Am. J. Hypertens. 2011;24:1312-1317)

Page 7: “We examined data for face validity with established age and gender associations in the whole sample dataset and separately in a sample of participants with a systolic BP <140 mmHg”

Could the face validity of the data be proved by showing the similar associations with age and gender?

Page 7: Data from 110 participants were excluded due to missing or erroneous values with analysis therefore performed on data from 1,793 volunteers.” This represents 5.8% of participants. Reasons and characteristics should be provided to analyze the feasibility of this device especially when application to this particular subgroup of subjects is encountered.

Figure 1 and 2: Symbols described in the legend do not match those in the figure.

Figure 1 and 2: central SBP and PP appeared to track brachial SBP and PP perfectly. This means that the difference between central and peripheral blood pressures was only an “off-set”. In fact, It has been shown that central SBP has a steeper relationship with age as compared to brachial SBP (J Am Coll Cardiol. 2005 Nov 1;46(9):1753-60, Figure 1).

Table 1: Younger subjects (age<30 years) usually have a type C central pulse wave form and therefor a very small or negative AIx. Therefore, the mean values of AIx presented in the present paper (15 for men and 23 for women) are too high.

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- Discretionary Revisions

1. page 5: “The ARCSolver method is commercially available in the oscillometric Mobil-O-Graph NGR 24-hour ambulatory BP and PWA monitor (IEM; Stolberg, Germany).”

It is unclear whether a “PWA monitor” is a laptop or not. If it is not equipped inside the oscillometric BP monitor, will it influence the “feasibility” of execution?
Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

Microlife Co., Ltd., and National Yang-Ming University have signed a contract for transfer of the noninvasive central blood pressure technique.