BP Monitoring during Dialysis at the University of Virginia Kidney Center

As part of a study at the University of Virginia Kidney Center 45 chronic kidney disease (CKD) dialysis patients were evaluated. The UVA main dialysis unit is comprised of 5 pods with each pod able to dialyze 6 patients simultaneously. After obtaining informed consent baseline blood pressure was obtained at the start of the dialysis treatment and then assessed every 15 minutes for the first hour, every half hour for the second and third hour and then every 15 minutes during the last hour of dialysis. All patients typically are dialyzed either sitting or reclining in a dialysis chair but begin dialysis in the sitting position.

Changes in position were based upon patient preferences or the need for Trendelenberg for severe inter-dialytic hypotension. No changes were made in the routine management of the dialysis patients nor were any additional standard laboratory values taken during or after dialysis other than routine dialysis labs or emergent labs based on their clinical condition. Most patients had their dialysis through their non-dominant arm and blood pressure was taken from the contralateral arm so as not to occlude their dialysis access. Blood flow, dose and duration of dialysis were according to standard practice and were not altered for the study. Typical dialysis

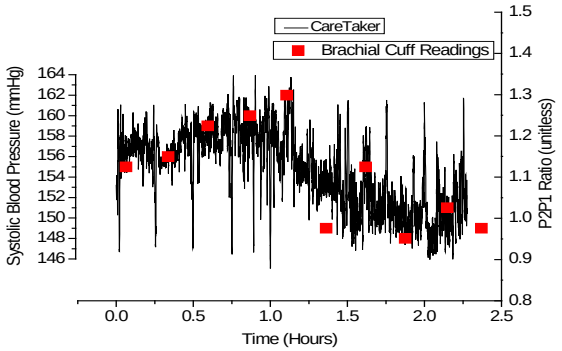

Figure 1: Trends in brachial cuff systolic pressure (red squares) and P2P1 over a 2.25 hr dialysis session (patient 17).

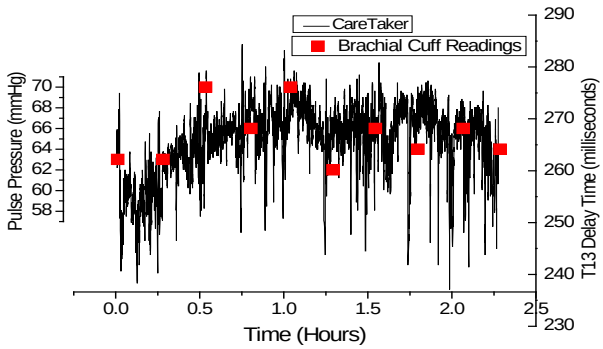

Figure 2: Trends in brachial cuff pulse pressure (red squares) and T13 over a 2.25 hr dialysis session (patient 17).

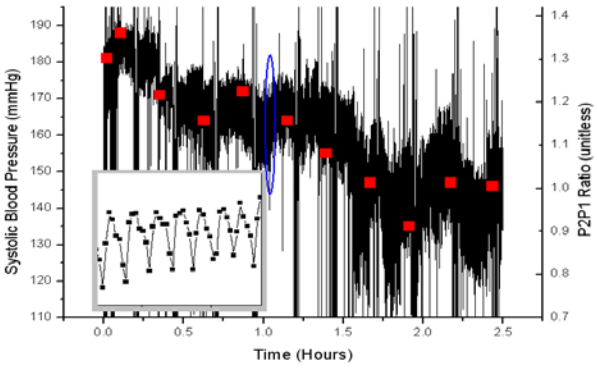

Figure 3: *Trends in brachial cuff systolic pressure (red sq.) and P2P1 over a 2.25 hr dialysis session (pt. 24). Detail inset displays inspiratory-based modulations.*

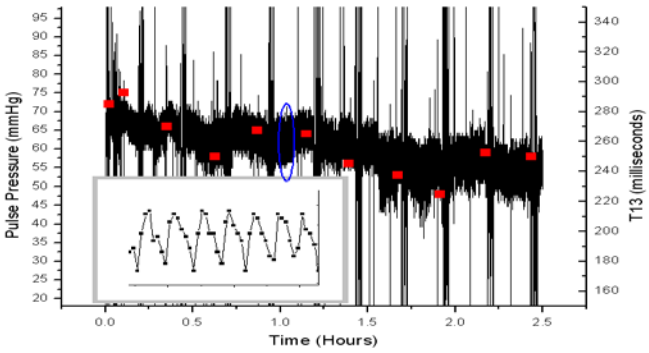

Figure 4: *Trends in brachial cuff pulse pressure (red sq.) and T13 over a 2.25 hr dialysis session (pt. 24). Detail inset displays inspiratory-based modulations.*

lasted 4 hours during which time the CareTaker recorded measurements. Each patient was monitored once. Besides blood pressure and pulse monitoring, demographic data including age, gender, race and ethnicity, cause and duration of ESRD (end-stage-renal-disease), prior history of other vascular disease, weight, height and BMI, tobacco use, socioeconomic status was also collected.

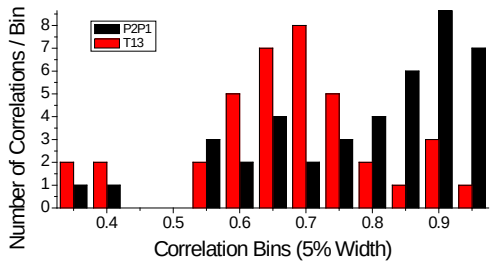

Figure 5: Distribution of correlation coefficients for P2P1 / cuff systolic pressure (black) and T13/cuff pulse pressure (red).

As an example, **Figures 1 & 2, 3, & 4** present systolic and pulse pressure measurements, respectively, obtained from the brachial automatic cuff as well as the corresponding pulse parameters P2P1 and T13 obtained from the PDA algorithm during a 2.5 hour dialysis run of patient 17. Comparable temporal trends in systolic pressure can be seen in the evolution of P2P1 and the same appears to hold for pulse pressure and T13.

The original plan was to examine different groups of dialysis patients, separated according to their history and presence of diabetes and hypertension. In light of the comparison results of the automatic brachial cuffs with the aortic catheter as well as the LBNP experiments, which demonstrated the cuffs' large variability in readings, it was decided to instead analyze all patient results together since the primary aim of the study was to validate the PDA technology as a generally applicable continuous blood pressure monitoring technology. Data from one patient with Parkinson's disease could not be analyzed as the patient's tremors introduced too much noise. In two other patients sections of the data run were corrupted because inappropriately sized finger cuffs were used. Overall analyzable signals were obtained about 92% of the time.

For individual patient runs the systolic pressure determined by the automatic cuff and the PDA P2P1 ratio determinations based on the CareTaker data were linearly correlated. Similarly, correlations between cuff-based pulse pressure and the PDA T13 parameter were determined. These correlations ranged from 0.98 to 0.38 (mean: 0.78) in the case of P2P1 – systole correlations and 0.96 to 0.37 (mean: 0.67) in the case of T13 – pulse pressure correlations. **Figure 5** presents a histogram, with 5% bins, displaying the distribution of the correlation coefficients. Given the effectively summed uncertainties of determining systolic and diastolic blood pressures with an automatic cuff, the poorer correlations for pulse pressure are not surprising.

Figures 6 and **7** present the overall results of correlating the dialysis runs. Paired readings were obtained by using the correlations obtained above to convert P2P1 and T13 determinations into systolic and pulse pressures, respectively. 229 pressure pairs, obtained every 15 minutes, were obtained from 45 patients, corresponding to 95 hours of data collection, or 2.12 hours/patient. Paired two-sample lower-tailed t-tests were used to establish statistical significance. The null hypothesis, which in both cases was that the difference in means exceeded 2 mmHg, could be rejected for both systolic and pulse pressure comparisons at a level of significance of 0.05 (paired systolic: $t = -4.08$, $p<0.00003$, confidence interval (95%): (-2.21, 0.53), power: 0.99), paired pulse pressure: $t = -3.09$, $p<0.0011$, confidence interval (95%): (-1.53, 1.22), power: 0.92).

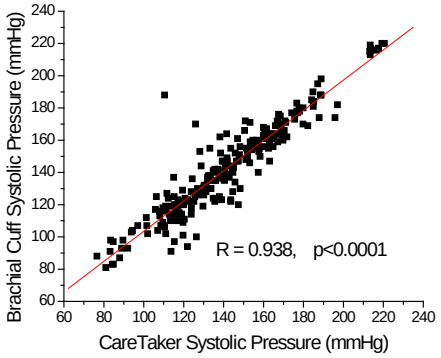

Figure 6: Overall correlation of systolic pressures from dialysis runs.

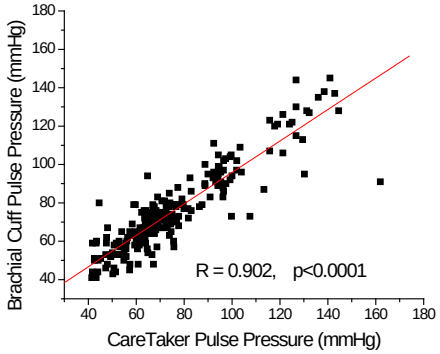

Figure 7: Overall correlation of pulse pressures from dialysis runs.

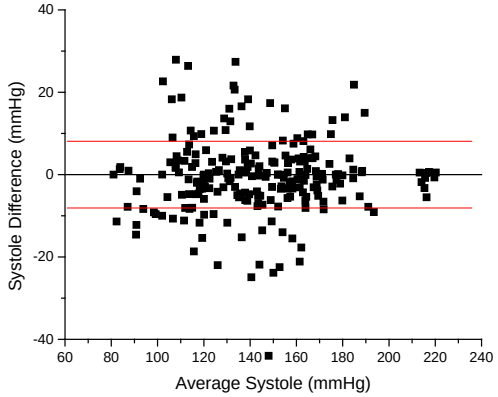

Figure 8: Overall Bland-Altman comparison of systolic pressures. Mean difference: 0.57 mmHg, standard deviation: 8.10 mmHg.

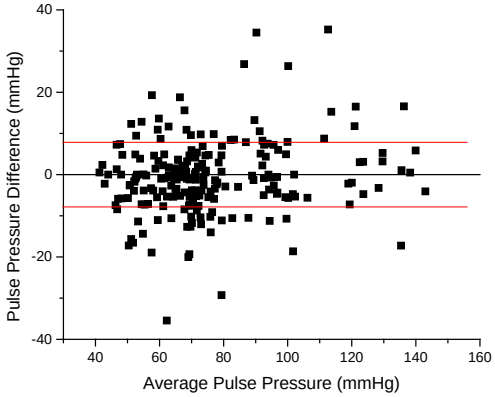

Figure 9: Overall Bland-Altman comparison of pulse pressures. Mean difference: -0.52 mmHg, standard deviation: 7.84 mmHg.

Figures 8 & 9 present a Bland-Altman comparison of, respectively, systole and pulse pressure obtained from the Gold Standard brachial cuff system. It is important to note, however, that the ***methodology of this comparison exceeds the required specifications of the AAMI SP10 (ANSI/AAMI 81060-2:2013) standard***. This is due to the fact that the standard calls for the comparison of the device-to-be-tested with TWO reference devices, whereas here a single reference device comparison was performed. Readings of the device-to-be-tested, according to the standard, are compared to the ***range*** established by the two reference device, which must not exceed 12 mmHg systole or 8 mmHg diastole. Readings within the range are assigned a standard deviation of zero. The comparison here is therefore more stringent because the range equals zero.

Conclusions

Comparison studies against automatic brachial cuffs during dialysis sessions of 45 patients were performed and yielded statistically significant correlations. Because of the uncertainties in cuff-determined blood pressures no attempt was made to analyze patients' data separately according to their history and presence of diabetes and hypertension.