Clinical Evaluation of an Oscillometric NIBP Technology During Hemodialysis According to the British Hypertension Society Protocol

Abstract

Objectives
Existing concerns over the accuracy of automated blood pressure measurement on hemodialysis patients illustrates a need for a proven non-invasive blood pressure (NIBP) technology for monitoring during hemodialysis. We investigated an oscillometric blood pressure technology from SunTech Medical designed for end-stage renal disease (ESRD) patients during hemodialysis using a modified British Hypertension Society (BHS) protocol.

Methods
Evaluation of the Advantage™HDM NIBP monitoring technology from SunTech Medical was performed against manual auscultatory observer readings using the grading criteria of the British Hypertension Society protocol. 85 subjects were included in the study giving a total of 255 data pairs for comparison. Readings were made using simultaneous same-arm measurement with observers using a dual-head stethoscope and a calibrated mercury sphygmomanometer as a reference to the Advantage HDM technology.

Results
The mean differences and standard deviations were exceptionally close with -0.03±5.4 and 0.44± 5.0 for systolic and diastolic blood pressure respectively. With 71% of all systolic blood pressure reference vs. technology differences equal to or less than 5mmHg, and 72% of all similar differences for diastolic pressure equal to or less than 5mmHg, the Advantage HDM technology received an A grade for both systolic and diastolic blood pressure measurement per the BHS grading criteria.

Conclusion
The Advantage HDM technology achieved an A/A grade for systolic and diastolic blood pressure measurement. As the population for this evaluation was exclusively ESRD patients during hemodialysis treatment, the Advantage HDM non-invasive blood pressure monitoring technology can be recommended for clinical use during hemodialysis.
Introduction
The gold standard for blood pressure measurement in any environment has long been manual readings taken with a mercury sphygmomanometer. However, with environmental concerns over the associated hazards of mercury and growing demands on limited personnel, many clinics have incorporated the use of automated oscillometric blood pressure monitoring. Accuracy of automated blood pressure measurements on end-stage renal disease (ESRD) patients during hemodialysis has not been well studied and there is currently cause for concern that routine automated measurements do not provide an accurate representation of blood pressure during treatment [1-3]. A recent study by Rahman et al. [2] showed a dramatic discrepancy between readings obtained with automated monitors in the dialysis unit and those obtained manually using standardized procedures. These findings highlight a need for a non-invasive blood pressure (NIBP) technology with proven accuracy for assessment of blood pressure during hemodialysis.

Monitoring blood pressure is vital to providing proper care for patients during hemodialysis. The most common complication experienced by ESRD patients during hemodialysis is a sudden drop in blood pressure [4]. Multiple studies suggest this intradialytic hypotension occurs in 25-50% of all hemodialysis sessions and can cause patients to suffer cramps, nausea and vomiting and in some cases cardiac ischemia or even vascular collapse [4-6]. In order to counteract this occurrence, blood pressure is frequently monitored and plays a significant role in adjusting treatment factors such as rate of water removal through ultrafiltration, dialysate concentration levels, assessment of dry weight, temperature of dialysate and length and/or frequency of treatment sessions [5].

Although frequent and accurate blood pressure monitoring during hemodialysis is considered essential, clinicians have not been able to overcome the numerous sources of measurement error associated with it. While variability in manual measurement is always a factor [7], the most complicated sources of error are specific to the ESRD patient population. Hemodialysis patients often have extensive cardiovascular disease and abnormalities that contribute to the development of vascular instability making assessment of blood pressure problematic. Further complicating the situation are arteriovenous grafts and fistulas which influence hemodynamic properties that can affect the accuracy of both automated and manual blood pressure measurement [1,3].

In an effort to overcome these obstacles, an oscillometric NIBP technology has been developed specifically for monitoring blood pressure during hemodialysis treatment. Given the characteristics of ESRD patients, the physiological complications of hemodialysis and the documented difficulty in achieving agreement between manual and oscillometric readings during treatment [2,3], a validation procedure is important to ensure accuracy of the technology as compared to standard manual measurements. This work investigates the performance of an automated NIBP monitoring technology under the conditions of hemodialysis treatment within an ESRD patient population using a modified British Hypertension Society (BHS) protocol [8].

Methods
NIBP module and test equipment
SunTech Medical (Morrisville, NC USA) has developed an automated oscillometric NIBP monitoring technology designed specifically for use on patients during hemodialysis treatment. This application specific technology can be incorporated on any of the Advantage OEM series of oscillometric NIBP module platforms available from SunTech Medical. Two Advantage 2.0 modules were used for this evaluation. Both modules were loaded with firmware incorporating the SunTech Medical hemodialysis monitoring technology (Advantage HDM). The Advantage 2.0 module measures blood pressure using the oscillometric method with step deflation. The blood pressure recording range is 40-260 mmHg for Systolic and 25-200 mmHg for Diastolic. A laptop PC was connected to each module to control operation and save collected data. The modules were set for normal deflation with a restrictor placed in the pneumatic manifold to allow the observers to obtain accurate manual measurements without interfering with the normal operation of the module or firmware. Two 3M Littman Master II Series teaching stethoscopes and 2 calibrated mercury sphygmomanometers were used for the manual blood pressure measurements.

Subjects
Subjects were recruited from the dialysis clinic at Dr. Georges-L. Dumont Regional Hospital (Moncton, New Brunswick, Canada). The study was approved by both Health Canada and the Hospital’s ethics review board. All subjects were adult volunteers with ESRD currently receiving hemodialysis treatment. Each subject was considered clinically stable and suitable as evaluated by the attending care team and each received written informed consent prior to testing. Subjects were excluded from the study if they had no palpable brachial pulses for blood pressure measurement, if Korotkoff sounds could not be heard by observers or if there was no clear phase 5 Korotkoff sound signaling diastole. Subjects were not excluded, however, if they had occurrences of atrial fibrillation or other heart rhythm disorders as this is common with ESRD patients [6,9] and is a regular challenge for routine monitoring of blood pressure during hemodialysis. This is unlike previous evaluation studies of oscillometric non-invasive blood pressure monitors that excluded any subjects with atrial fibrillation or other sustained arrhythmias [3,10].
Blood Pressure Measurement

All four observers, two teams of Observers 1 & 2, were trained for proper technique in auscultatory blood pressure measurement according to the criteria of the BHS protocol using the BHS training video “blood pressure measurement”. All subjects were undergoing hemodialysis treatment during the time of blood pressure measurement. Subjects were either reclined in a dialysis chair or lying in a standard hospital bed and rested still for a 10 minute period before blood pressure readings began. After measuring arm circumference, the appropriate size cuff was selected and put on an available upper arm. All cuffs used in the evaluation were manufactured by SunTech Medical. Many dialysis patients have IVs, so cuffs were placed on available arms without an IV. Once the appropriate arm was selected, the blood pressure cuff was placed around the upper arm with the stethoscope placed over the brachial artery just below the cuff and wrapped in place with an elastic ACE bandage. The elastic bandage kept the observers’ hands free of the stethoscope in an effort to reduce artifact and erroneous readings. Each measurement was initiated with the Advantage 2.0 module via the laptop PC. The module was set to inflate to 30 mmHg above the subject’s previously known systolic pressure. As the module controlled the inflation and deflation to make its determination of blood pressure, the observers simultaneously made reference auscultatory measurements using Korotkoff phase 1 (onset of K-sounds) and Korotkoff phase 5 (cessation of K-sounds) for systolic and diastolic pressures respectively as recommended in section 4.4.5.1.b of the AAMI-SP10 guidelines [11]. Observers were blinded from each other and the Advantage HDM results during the manual measurements.

Protocol

The measurement process consisted of 5 simultaneous readings per subject. Although the BHS protocol calls for sequential observer and device readings, simultaneous readings were chosen to mitigate the high variability of blood pressures during hemodialysis treatment and to allow additional analysis by the AAMI-SP10 protocol. Furthermore, recent studies presented evidence suggesting simultaneous assessment of blood pressure accuracy is superior to sequential measurements [1]. The first reading served as a classification/calibration reading with the following four readings considered gradable readings. Three readings were required per subject to perform the grading analysis. This allowed for excluding any reading where the observer’s results differed by more than 4 mmHg. Any measurement where the observer’s results differed by more than 4 mmHg was excluded from the analysis. At least 30 seconds and no more than 60 seconds elapsed between each reading. Total time per subject was approximately 20-25 minutes. The observer results were recorded manually on separate data logs. Once the blood pressure had been determined by the Advantage HDM technology, the module’s results were saved to the laptop PC.

Analysis

Analysis of the collected data was done according to a modified Option 1 [13] of the BHS protocol. Traditionally, data is collected sequentially with differences calculated before and after observer/device readings. However, because the data for this evaluation was collected simultaneously and each data point from each of the four observers is compared to the result from the Advantage HDM technology independently, there is a score for Observer 1 and a score for Observer 2. The accuracy criteria are based on the percentages of automated measurements differing from the individual observer results as shown in Table 1.

Table 1 Grading criteria of blood pressure device by percentage of differences according to BHS protocol [8]

<table>
<thead>
<tr>
<th>Grade</th>
<th>Difference between observer and device (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤ 5</td>
</tr>
<tr>
<td>A</td>
<td>60</td>
</tr>
<tr>
<td>B</td>
<td>50</td>
</tr>
<tr>
<td>C</td>
<td>40</td>
</tr>
<tr>
<td>D</td>
<td>Below a C</td>
</tr>
</tbody>
</table>

A total of n=255 data points are considered, (85 subjects x 3 data points/subject = 255). These percent differences fall into three categories; ≤5, ≤10, and ≤15mmHg. Grading is based on the number of differences within these categories. Systolic and diastolic grades are determined independently. The Advantage HDM technology was graded A, B, C or D separately for each observer, then the most favorable observer grade is chosen for the final grade. Additionally, it is possible to choose the systolic grade from the results of one observer and the diastolic grade from those of the second observer.

Results

Subject Demographics

A total of 95 subjects participated in the study. 10 subjects were excluded from the analysis due to their meeting one of the criteria for exclusion explained earlier. Details of the remaining 85 included subjects are illustrated in Table 2. Child, Small Adult, Adult, Large Adult and Thigh size SunTech Medical All-Purpose cuffs were utilized for the data collection.

Interobserver variability

To meet the accuracy limits of the BHS protocol, 80% of observer readings must be within 5 mmHg and 95% of observer readings must be within 10 mmHg. For this evaluation study, 100% of the observer readings collected were within 5 mmHg of each other, well within the limits of the BHS protocol.
Table 2  Study population characteristics

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean ±SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (M:F)</td>
<td>58:27</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>67±13.46</td>
<td>33-87</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>169±9.53</td>
<td>137-185</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>78±20.88</td>
<td>35-145</td>
</tr>
<tr>
<td>Arm circumference (cm)</td>
<td>29±4.29</td>
<td>18-44</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>121 ± 20</td>
<td>72-178</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>63 ± 11</td>
<td>40-90</td>
</tr>
</tbody>
</table>

SD (standard deviation); M (Male); F (Female); SBP (systolic blood pressure), DBP (diastolic blood pressure).

Table 3  Mean and mean difference for AdvantageHDM and overall results from both observers.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage of differences between standard and test module (mmHg)</th>
<th>Mean ± SD of differences (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤ 5</td>
<td>10</td>
</tr>
<tr>
<td>Observer 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SBP</td>
<td>A</td>
<td>70</td>
</tr>
<tr>
<td>DBP</td>
<td>A</td>
<td>72</td>
</tr>
<tr>
<td>Observer 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SBP</td>
<td>A</td>
<td>71</td>
</tr>
<tr>
<td>DBP</td>
<td>A</td>
<td>72</td>
</tr>
<tr>
<td>Final Grade</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SBP</td>
<td>A</td>
<td>71</td>
</tr>
<tr>
<td>DBP</td>
<td>A</td>
<td>72</td>
</tr>
</tbody>
</table>

SBP, systolic blood pressure; DBP, diastolic blood pressure

BHS Grading
Calculations of the collected data yield the summary of results shown in Table 3. The mean differences between the observer and Advantage HDM technology readings were exceptionally close. Observer 2 was the most favorable yielding a -0.03 ± 5.4 and 0.44 ± 5.0 for systolic and diastolic pressures respectively.

The final grade is determined by the observer readings with the most favorable result, therefore Observer 2 is chosen for both the systolic and diastolic results. With 71% of all SBP reference vs. technology differences equal or less than 5 mmHg and 72% of all similar DBP differences equal or less than 5 mmHg, the Advantage HDM NIBP monitoring technology clearly passes the BHS protocol with an A/A grade.

The Bland-Altman graphs (Figures 1 & 2) display the differences against averages for systolic and diastolic between the Advantage HDM technology and the observer reference. The graphs show that the technology and observer differences do not increase with higher systolic (diastolic) readings and do not become more positive or negative with high or low systolic (diastolic) measurements.

Discussion
With difficulties of accurately assessing blood pressure for ESRD patients during hemodialysis being well documented [1-5,7,12], clinical performance of a hemodialysis specific oscillometric blood pressure technology should be confirmed within the intended population and environment. The British Hypertension Society encourages evaluation of blood pressure devices in special patient populations and circumstances, but does not require the complete 85 patient protocol be performed within the specific population or circumstance [8]. The results of our evaluation show the Advantage HDM technology achieves the highest rating for clinical accuracy according to the BHS grading criteria on a complete 85 patient population tested exclusively under the specific conditions of hemodialysis on an ESRD patient population.

The primary complication encountered in this study was related to the limitations of the available subject population. While it was considered a primary objective to measure performance of the technology specifically on ESRD patients during hemodialysis, it prevented the subject enrollment from meeting all the distribution requirements for each blood pressure group of the BHS protocol. The blood pressure range requirements of the BHS protocol calls for at least 8 subjects with an initial systolic reading greater than 180 mmHg and 8 subjects with a diastolic reading greater than 110 mmHg. In this study, there were no subjects that exhibited classification pressures in those categories. This data collection also fell short in the 161-180 mmHg systolic range where only 2 subjects were classified in this group.
Difficulty identifying subjects in the hypertensive range was anticipated as this study focused only on ESRD patients during hemodialysis. A significant drop in blood pressure is common during hemodialysis due to the abrupt removal of fluid which lowers blood volume and disrupts the balance between cardiac output and total peripheral vascular resistance \[6,12\]. This was further demonstrated by 29 subjects being classified in the lowest diastolic range of less than 60 mmHg. The BHS protocol only requires 8 subjects for this category. Despite the fact that subject distribution did not meet all the blood pressure range requirements of the BHS, the tradeoff was made to focus on subjects during hemodialysis treatment to provide a more relevant assessment during intended use rather than meeting the ranges originally designed for a general population evaluation.

Other modifications to the BHS protocol that should be pointed out are the omission of the in-use field assessment, (phase II), and after-use calibration, (phase III) of the tested devices. The Advantage 2.0 modules selected for testing successfully completed the before-use calibration (phase I) and then proceeded to the static device validation procedure (phase IV). Since the modules selected with the Advantage HDM technology had been through the extensive burn-in test and other quality inspection procedures of SunTech Medical’s standard manufacturing process, we felt the use and testing intended by phase II and III were not necessary. We do not believe these modifications compromise the integrity of the results of this study. In fact, two specific deviations from the BHS protocol that were incorporated in this study — the inclusion of patients with arrhythmias and the use of simultaneous observer/device measurements — serve to strengthen the results.

The British Hypertension Society protocol suggests that patients with arrhythmias (such as atrial fibrillation) should not be included in the evaluation \[8\]. However, there is a very high incidence of cardiac arrhythmias within the ESRD population which is exacerbated by the rapid electrolyte changes during hemodialysis sessions \[6\]. Although this certainly complicates both manual and automated blood pressure assessment, it is a significant attribute of ESRD patients and should be considered when evaluating the performance of an automated blood pressure monitoring technology for use during dialysis treatment. Additionally, research has shown that ESRD patients with cardiac arrhythmias during hemodialysis exhibit reduced arterial compliance and can contribute to unstable blood pressures \[9\]. It is primarily because of this blood pressure variability that simultaneous observer and device readings were chosen instead of the sequential practice outlined in the BHS protocol. In fact, work by Semret et al. \[1\] recently presented evidence that suggests simultaneous assessment of an oscillometric device to an auscultatory reference is superior to sequential measurements. Additional benefits to collecting automated measurements while simultaneously recording the observer reference readings, is that it allows further clinical evaluation to the AAMI SP10 protocol as well as possible future technology enhancements.

The reduced arterial compliance that has been shown to occur in patients during hemodialysis was a concern since this has been shown to affect pulse pressure amplitudes and can have a strong influence on the accuracy of oscillometric blood pressure monitoring \[10\]. Another cause for concern was the presence of arteriovenous fistulas and grafts for dialysis access which may introduce hemodynamic changes that can influence blood pressure measurement \[1\].

**Fig 1.** Systolic pressure: Bland-Altman graph of the difference between the chosen observer and the Advantage HDM module vs. the average pressure for the module and the observer in all 85 subjects (n=255).

**Fig 2.** Diastolic pressure: Bland-Altman graph of the difference between the chosen observer and the Advantage HDM module vs. the average pressure for the module and the observer in all 85 subjects (n=255).
However, neither of these obstacles seemed to interfere with the Advantage HDM technology from achieving agreement with the manual observer blood pressure measurements. Variability between the observer readings also showed a high level of agreement.

Although recommended, current validation protocols and guidelines do not require automated blood pressure monitors to be validated on specific patient populations. Consequently, most are validated on readily available healthy volunteers. In this regard, special efforts have been made here by focusing not only on ESRD patients, but in the environment for which the technology was intended by performing the evaluation during hemodialysis treatment. The only other oscillometric blood pressure device we are aware of to be evaluated in an ESRD population during hemodialysis was performed by Peixoto et al. [3] on an ambulatory blood pressure monitor which achieved grades of C for systolic pressure and B for diastolic pressure. The Advantage HDM oscillometric blood pressure technology received an A grade for both systolic and diastolic according to the BHS grading criteria. It is also noteworthy that subjects with sustained arrhythmias were excluded from the evaluation of the ambulatory device, while similar subjects were purposefully included in our evaluation.

Given the numerous physiological challenges of assessing blood pressure in the ESRD patient population during hemodialysis, we feel the modifications made to the BHS protocol were not only acceptable, but serve to provide a more relevant representation of how the blood pressure technology performs under the conditions in which it was designed to be used. As a result, the Advantage HDM NIBP monitoring technology from SunTech Medical has proven to achieve the British Hypertension Society’s highest level of accuracy for monitoring blood pressure of ESRD patients during hemodialysis.

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