Evaluation of a Non-Invasive Blood Pressure Monitoring Technology During Emergency Transport Conditions as Compared to the ProPaq LT

Abstract

Objectives

In most emergency transport environments, both patients and medical equipment are exposed to unstable circumstances due to the vehicle's movement and vibration. The noise and motion artifact generated often make it difficult to obtain a successful automated blood pressure reading. To address these complications, SunTech Medical has developed an oscillometric NIBP technology designed specifically for emergency transport applications. We performed a clinical evaluation of this technology and compared it to a recognized market leader for monitoring vital signs during emergency transport.

Methods

This clinical evaluation compared the performance of the Advantage™ Transport Motion Tolerant (TMT) NIBP technology from SunTech Medical against blood pressure measurements made by the Welch Allyn ProPaq LT under emergency transport conditions. A total of 45 subjects participated in this study giving 450 total data points for inter-device comparison.

Results

The ProPaq LT provided successful blood pressure measurements on 96.2% of all attempts while the *Advantage* TMT technology achieved a higher measurement success rate of 98.4%. On average, the ProPaq LT required 42.6 ± 23.2 seconds to complete a successful reading, while the *Advantage* TMT technology achieved a quicker and more consistent average reading time of 36.3 ± 15.0 seconds. Both devices performed well when compared to manual reference readings, however the ProPaq LT showed standard deviations considerably higher than the *Advantage* TMT technology.

Conclusion

When tested under typical circumstances for emergency transport, the *Advantage* TMT NIBP technology consistently reported blood pressure readings at a quicker and more reliable rate than the ProPaq LT. The *Advantage* TMT also demonstrated significantly less variability than the ProPaq LT without compromising overall accuracy.

Introduction

Motion artifact resulting from patient movement is a significant source for disturbing accurate noninvasive blood pressure (NIBP) measurement. In an ambulance, patients are exposed to unstable circumstances due to the vehicle's movement and vibration during emergency transportation.

Since oscillometric NIBP is an indirect measurement of cuff pressure changes, it can be affected by motion artifact much more than biosignals [1]. Since acquiring a manual blood pressure measurement is often too difficult in the emergency transport environment, a reliable alternative is required. In an emergency transport setting, it is imperative to achieve quick and reliable blood pressure readings while minimizing error codes and failed reading attempts.

In order to address these needs, SunTech Medical (Morrisville, NC USA) has developed an oscillometric NIBP technology designed specifically for emergency transport situations. This clinical evaluation compared the performance of the SunTech Medical Advantage™ Transport Motion Tolerant (TMT) NIBP technology against the Welch Allyn ProPaq LT, a multi-parameter device often utilized for blood pressure measurement in emergency transport settings.

Methods

Subjects

The subjects for this study were local volunteers recruited by SunTech Medical. 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.

NIBP module and test equipment

SunTech Medical has developed an automated oscillometric NIBP technology designed for performance within the emergency transport environment. This application specific technology can be incorporated on any of the *Advantage* OEM series of oscillometric NIBP module platforms available from SunTech Medical. An *Advantage* 2.0 NIBP module was used for this evaluation. 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 the module to control operation and save collected data. One 3M Littman Master II Series teaching stethoscope and one calibrated aneroid manometer were used for the manual blood pressure measurements. Calibration verification was performed on both the *Advantage* TMT module and the ProPaq LT device before data collection began.

Observer training

Two observers were trained according to the instructional CD-ROM produced by the British Hypertension Society (BHS). Prior to testing, the observers also went through a process of familiarization using the *Advantage* TMT module and ProPaq LT device. Each machine was a standard production model. The familiarization session enabled the observers to gain experience in using the *Advantage* TMT module and ProPaq LT device and to confirm that both were performing well and without idiosyncratic problems.

Procedure

Subjects were securely placed in the supine position on an ambulance stretcher in the back of a transport vehicle to best replicate the mobile ambulance environment. Arm circumference, gender and age were recorded for demographic purposes. This information, along with each blood pressure measurement, was recorded on data log sheets. The subject was allowed to relax, in the stretcher for a minimum of 5 minutes in order to allow for blood pressure stabilization. A total of 13 sequential readings were taken using an aneroid manometer and the two devices.

The 1st, 7th, and 13th readings were taken manually, using an aneroid manometer and stethoscope while the vehicle was idle. This ensured that the observers could distinctly hear the Korotkoff sounds. The blood pressure cuff was wrapped securely around the subject's left arm, 1-2 inches above the antecubital fossa. The middle of the bladder was located directly over the brachial artery. With these manual readings, the cuff was inflated to a pressure high enough to occlude the brachial artery and then deflated at a rate of 3-5 mmHg/second. The manual readings were always taken on the left arm.

A total of ten automated readings (Readings 2-6 and 8-12) were taken simultaneously with the *Advantage* TMT module and ProPaq LT device. Five readings were taken on the subject while driving on gravel at a speed of 20 miles/hour (mph). Five readings were taken on the subject while on a paved street/highway conditions at speeds between 45 and 60 mph. The ProPaq LT cuff was placed on one arm and the *Advantage* All-Purpose Cuff (APC) was placed on the opposite arm. The observers would then start both the *Advantage* TMT and ProPaq LT measurements simultaneously. After both units had deflated and measurements were complete, the reading information was recorded into the data log. Systolic pressure, diastolic pressure, heart rate (HR), and reading duration were recorded. The devices and cuffs were alternately placed on the subjects' left and right arms for randomization purposes.

Analysis

The gold standard of determining accuracy of NIBP is by auscultation with trained professionals. However, this has proven to be an inaccurate method of taking blood pressure measurements in the emergency transport environment [2]. Since no clinical validation protocol exists for assessment of

Table 2 Comparison of Measurement Duration

		Advantage TMT	ProPaq LT
Highway	Avg. Time (sec)	32.5	38.9
	SD	11.6	16.8
	Range (sec)	17 – 100	21 - 149
Gravel	Avg. Time (sec)	40.0	46.3
	SD	16.8	28.0
	Range (sec)	16 – 106	21 - 210
Overall	Avg. Time (sec)	36.3	42.6
	SD	15.0	23.2
	Range (sec)	16 – 106	21 - 210

automated blood pressure measurement during emergency transport conditions, it is important to note that this comparative study was not performed in accordance with any regulatory protocol (i.e. BHS, ESH International, or AAMI SP10). Consequently, the procedure previously outlined was created by the SunTech Medical staff in an attempt to specifically and fairly evaluate the *Advantage* TMT technology and ProPaq LT device in the emergency transport environment.

Comparisons of the percentage of successful readings (no error code reported) and reading duration were made between the *Advantage* TMT module and ProPaq LT device. The success rate was calculated by dividing the number of successful blood pressure measurements by the total number of blood pressure measurements taken (n = 460). The average and standard deviation of the reading duration data were calculated for both the *Advantage* TMT module and ProPaq LT device.

The manual readings were to serve exclusively as a 'baseline' to make general comparisons of the systolic and diastolic results between the two devices. For each subject, the 1st and 7th manual readings were averaged and subtracted from each of the automated readings 2-6. Likewise, the 7th and 13th manual readings were averaged and subtracted from each of the automated readings 8-12 in order to calculate the mean difference and standard deviation.

Results

A total of 45 subjects participated in this study giving 450 total data points for inter-device comparison of automated blood pressure measurements. This does not include the manual readings used for general baseline comparisons.

Given the difficulty of blood pressure measurement in the emergency transport environment, obtaining a successful automated measurement is a significant factor by which to compare the *Advantage* TMT technology and the ProPaq LT device. This data is shown in Table 1.

Overall, a blood pressure measurement is considered successful when no error codes are produced and reports both a systolic and diastolic reading. If there is an error while taking a blood pressure measurement, the *Advantage* TMT will not report a systolic reading or a diastolic reading. Therefore, the *Advantage TMT* success rate is a constant 98.4% for both systolic and diastolic. If there is an error while taking a blood pressure with the ProPaq LT, the device may still report a single systolic or diastolic reading, explaining the difference in the systolic and diastolic reading success rates of 96.2% and 97.1% respectively.

Table 1 Success Rate Comparison

	Advantage TMT	ProPaq LT
Overall	98.4%	96.2%
Systolic	98.4%	96.2%
Diastolic	98.4%	97.1%

Because time to obtain a blood pressure measurement in an emergency transport scenario is also a significant factor, reading duration for each blood pressure measurement was analyzed. The overall average time of measurement for the *Advantage* TMT and ProPaq LT are displayed in seconds in Table 2.

Lastly, systolic (SBP) and diastolic (DBP) measurements for the *Advantage* TMT module and ProPaq LT device were compared to the average baseline manual readings. The mean differences along with standard deviations (SD) are shown in Table 3 for the *Advantage* TMT module and ProPaq LT device, respectively. The blood pressure measurement data was analyzed according to which surface the transport vehicle was traveling over at the time of data collection (Gravel or Highway) then analyzed for all measurements in total (Overall).

Table 3

	Overall	Gravel	Highway
Advantage TMT			
SBP	-0.95 ± 7.62	-0.74 ± 8.76	-1.15 ± 6.32
DBP	2.41 ± 6.74	3.25 ± 7.03	1.58 ± 6.34
ProPaq LT			
SBP	0.60 ± 10.18	1.23 ± 12.60	-0.09 ± 7.01
DBP	0.50 ± 12.81	0.52 ± 15.39	0.53 ± 9.74

Figures 1 and 2 are scatter plots of systolic and diastolic readings, respectively, for measurements made manually and by the two devices. Graphical markers located on the x-axis indicate failed reading attempts. As previously shown in Table 1, the *Advantage* TMT technology provided successful measurements on 98.4% of all attempted readings, while the

ProPaq LT achieved a success rate of 96.2% for systolic and 97.1% for diastolic.

Figure 3 shows a scatter plot for heart rate (HR) measurements made by the two devices. Again, markers located on the x-axis indicate failed readings. The ProPaq LT demonstrated a wider array of outlying measurements when compared to the *Advantage* TMT module.

Figure 4 illustrates the time elapsed for each blood pressure measurement by the two devices. When compared with the *Advantage* TMT module, the ProPaq LT device shows tremendous variability in regards to reading duration. In the instances that the ProPaq LT took an extended period of time to report a result, the result appeared erroneous.

Discussion

Auscultation or palpation of blood pressure in critically ill patients by emergency medical technicians (EMTs) can be difficult, if not impossible, because of ambient noise, motion artifact, limited access to patients, or weak pulses [2]. With quiet patients, NIBP devices provide clinically accurate readings in a wide variety of physiological conditions. However, pressure oscillations impinging on the cuff from sources other than the heart (such as transport vibration, shivering, and tremors, to name a few) may seriously degrade NIBP performance [3]. This degradation includes reduced accuracy, increased patient discomfort from prolonged measurement times and increased re-inflates, and most importantly misdiagnosis.

The very factors that produce motion artifact in the blood pressure cuff during transport also produce auditory noise, thereby preventing the verification of NIBP accuracy through the traditional auscultatory measurement method with a stethoscope. For these reasons, this comparative study aimed to further understand how these factors affect NIBP measurement with the *Advantage* TMT module and the ProPaq LT device in emergency transport situations.

In the emergency medicine environment, not only should the blood pressure measurement technology report accurate BP results, but also provide the results quickly and with minimal error code occurrences. When evaluating the amount of time each device required to successfully complete a BP measurement, the ProPaq LT presented a wider range of variability and inconsistency than the *Advantage* TMT. On average, the ProPaq LT needed 42.6 ± 23.2 seconds to complete a successful reading. Alternatively, the *Advantage* TMT technology needed only 36.3 ± 15.0 seconds to return a successful reading.

Both devices performed well in regards to mean differences compared to manual readings; however, the ProPaq LT demonstrated a greater degree of variability, as illustrated in Figures 1-4. Figure 3, a scatter plot of heart rate readings, exemplifies much of the inconsistency reported by the ProPaq LT which produced many high outlier readings suggesting the device may report inaccurate heart rate measurements due to triggered noise and motion artifact. Figure 4 illustrates the ProPaq LT device often required significantly more time to complete a successful blood pressure reading than the *Advantage* TMT.

The *Advantage* TMT technology produced more consistent results in more than one area of this study. When looking at the mean and standard deviation of the differences, the ProPaq LT (1.23 ± 12.60 mmHg) reported a standard deviation of nearly 50% greater then that of the *Advantage* TMT (-0.74 ± 8.76 mmHg) for SBP on gravel. Similarly, the ProPaq LT (0.52 ± 15.39 mmHg) reported a standard deviation more than double that of the *Advantage* TMT (3.25 ± 7.03 mmHg) for DBP on gravel. This is significant, assuming the surface provided the majority of motion artifact from mechanical vibration and patient movement. This, in turn, more accurately simulated the environment in which emergency transport NIBP is measured.

The protocol used for this study did not follow any recognized regulatory protocol due to the fact that no protocol exists for evaluation of automated blood pressure technologies in transport motion conditions. Given the numerous challenges for automated NIBP in the emergency transport environment, we feel the *Advantage* TMT technology was shown to function at a high level of consistency and certainty under the conditions in which it was designed to be used. Not only did the *Advantage* TMT technology consistently report quick and reliable readings, but it also demonstrated a significantly lower degree of variability when compared with the ProPaq LT.

Based on these results, the *Advantage* TMT technology from SunTech Medical performed blood pressure measurement at least as well as the Welch Allyn ProPaq LT under conditions of transport motion and in fact, surpassed it by exhibiting quicker readings, fewer failed reading attempts and less variability.

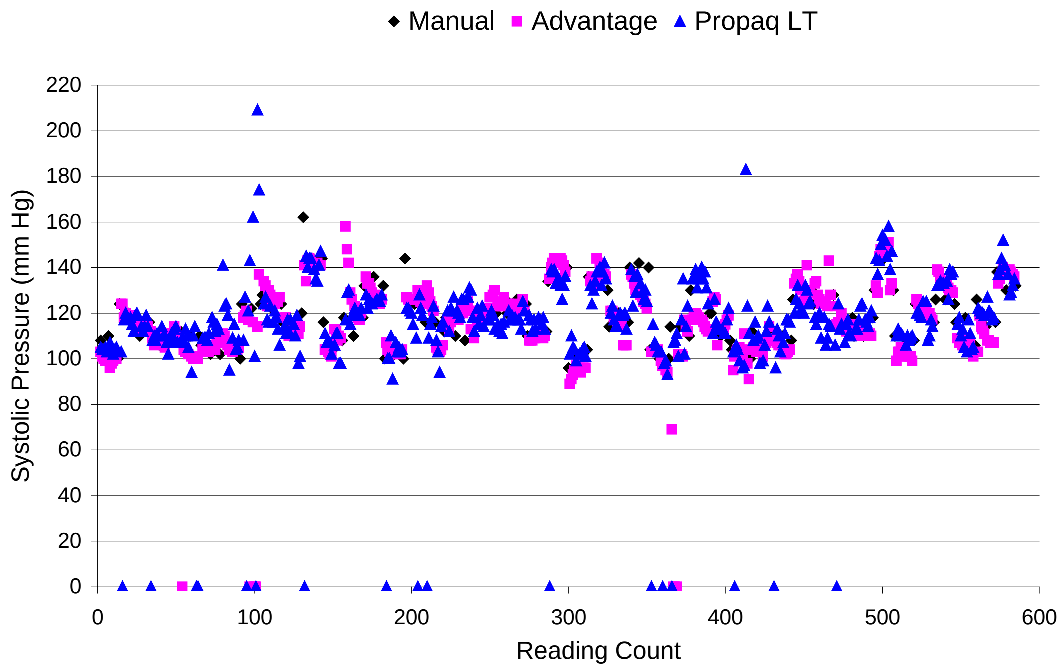

Figure 1. Scatter plot of systolic blood pressure readings in all subjects (n=45). Note: Markers along the x-axis indicate a failed reading.

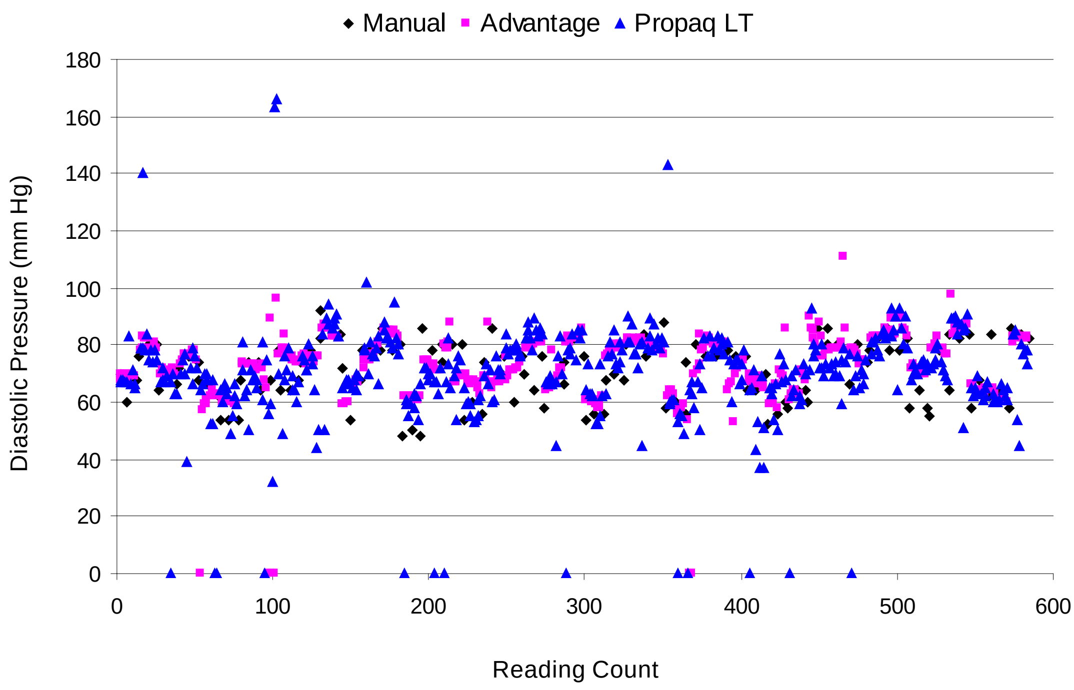

Figure 2. Scatter plot of diastolic blood pressure readings in all subjects (n=45). Note: Markers along the x-axis indicate a failed reading.

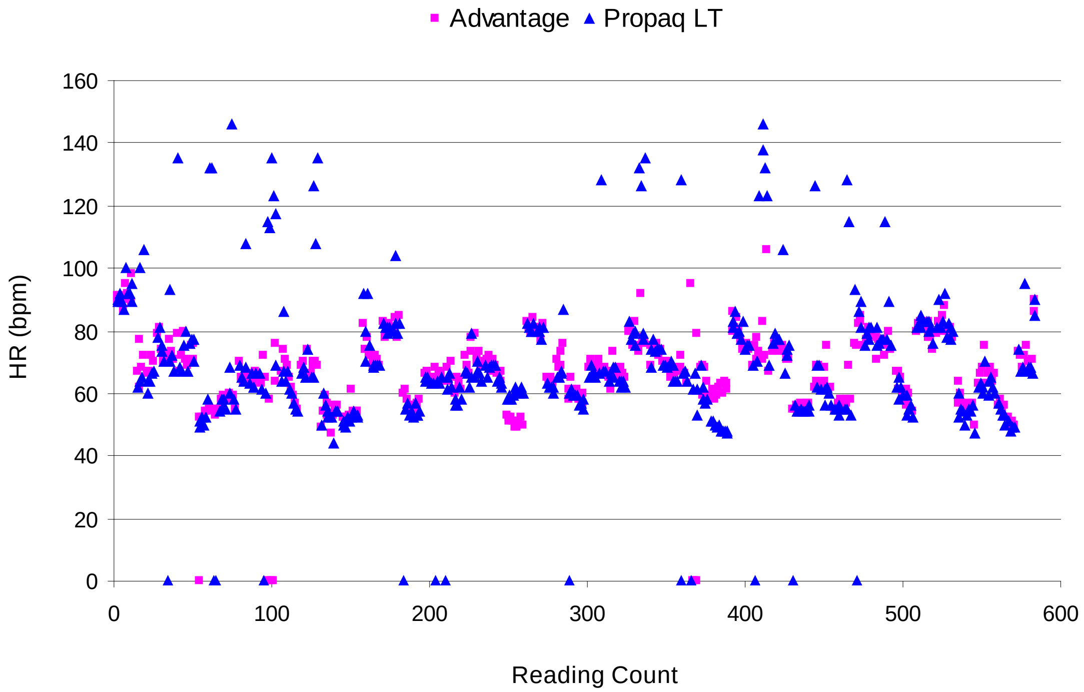

Figure 3. Scatter plot of heart rate readings in all subjects (n=45). Note: Markers along the x-axis indicate a failed reading.

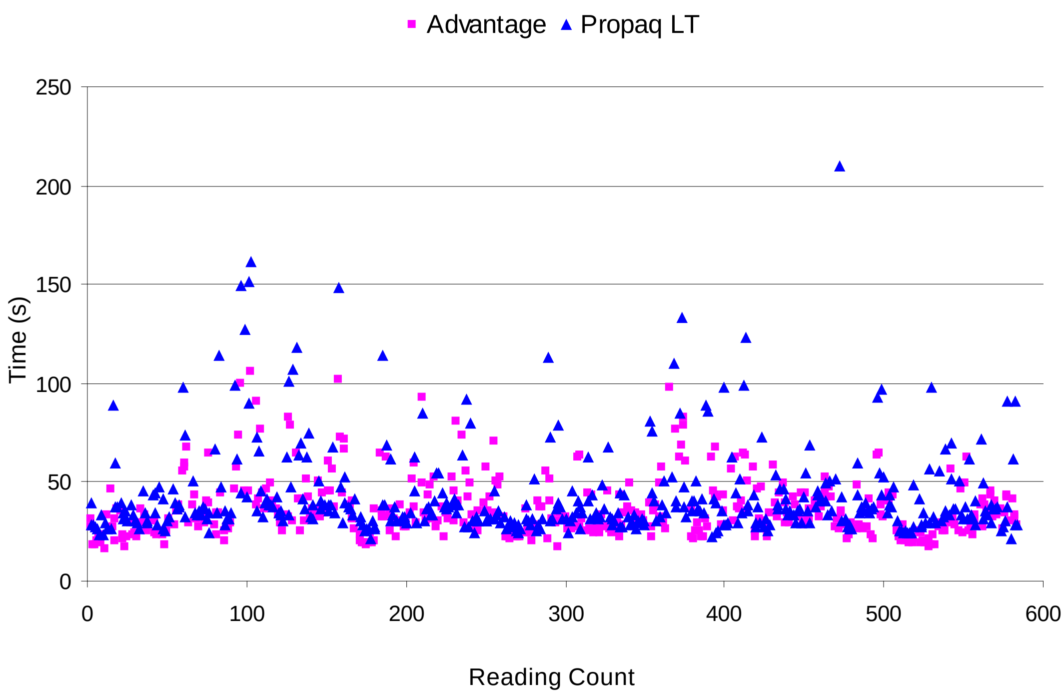

Figure 4. Scatter plot of device duration readings in all subjects (n=45).

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