Validation of the Saadat NIBP module according to the ANSI/AAMI-SP10 protocol

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***Abstract*—This study is conducted with the aim of validating the Saadat non-invasive blood pressure (NIBP) module accuracy and reliability against direct intra arterial pressure measurement (IBP) according to the ANSI/AAMI SP10-2002 guidelines. Measurement and comparison procedure were done in a static population of 19 adult patients with brachial catheterized arterial line with total measurements of 195 under supervision of a highly experienced cardiovascular anesthesiologist in accordance with the ANSI/AAMI SP10-2002 regulation. Data analysis was performed based on the protocol criteria. In order to represent relationships between the test device and the reference method, Bland-Altman graphical plotting method was used. The mean ± SD differences between the readings of Saadat NIBP device and IBP as the reference method for systolic, diastolic and map pressures were: -0.9 ± 6.95 mmHg for systolic, 2.57 ± 7.79 mmHg for Diastolic, and 3.89 ± 7.06 mmHg for Map. The Saadat NIBP module fulfilled the ANSI/AAMI SP10-2002 requirement that is the mean ± SD of lower than 5 ± 8 mmHg.**

Keywords-component; Saadat NIBP; IBP; Validation; AAMI SP10

I. INTRODUCTION

Blood pressure measurement plays an important role in clinical assessment of a patient condition, monitoring and controlling the medication procedure [1]. Invasive blood pressure monitoring (IBP) is one of the most common methods in continuous beat to beat measurement of a patient's blood pressure in the ICU wards and the operating rooms. Intra-arterial blood pressure measurement is made by direct insertion of a catheter into the artery line of a patient. In this system, a pressure transducer receives the patient pressure waveform by the aid of a tube of fluid and then converts it into a visual electrical signal for displaying on the monitor [2]. Beside invasive blood pressure measurement as a continuous beat to beat technique, non invasive blood pressure (NIBP) devices are applied as a routine technique in clinical practices due to some disadvantages of IBP method such as invasive inherency, arterial line infection and expensive equipments [2]. Among different non invasive techniques, mercury sphygmomanometer is considered as the gold standard by WHO guideline [3]. However, the mercury sphygmomanometer devices are banned for using in clinical environment due to their contamination and toxicity [1]. Nowadays, the oscillometric method as a substitute to the mercury sphygmomanometer is more common in hospital and home use settings [1]. The automated oscillometric devices generally function based on linear deflation or step deflation. Automated oscillometric devices with step deflation characteristic make measurement and monitors pressure based on the automatic controlled cuff inflation and step deflation procedure. After occluding the brachial artery by the inflated cuff which is around the patient's arm, deflation initiates in a step manner slightly above the expected patient's systolic pressure to a pressure lower than diastolic pressure. While the cuff is deflating, the oscillation amplitude of one pulse beat and then the amplitude of the pressure changes in the cuff are measured. These amplitude pressures changing are represented as an oscillometric amplitude profile (oscillation envelope). The maximum point of this envelop curve is considered as the map pressure and then the systolic/diastolic pressures are defined based on the obtained map pressure [4]. There are difficulties in choosing an accurate oscillometric device due to abundance of these equipments in the market and only a few of them has published evidences indicating studies to test the reliability and accuracy of their techniques. Different societies such as the AAMI, the Association for the Advancement of Medical Instrumentation, the BHS, British Hypertension Society and the ESH, European Society of Hypertension recommend guidelines and protocols for validating the oscillometric devices. According to the ESH, the devices failed to gain the acceptance of the AAMI protocol or achieved C/D grades based on the BHS guideline are not considered accurate and cannot be recommended for use [5]. The main objective of this study is to validate Saadat NIBP module as an automated oscillometric device against the intra- arterial technique following the AAMI SP10 protocol.

II. MATERIALS AND METHODS

According to the AAMI SP10-2002 standard criteria, the automated oscillometric devices must be validated against intra-arterial pressure (IBP) measurement which is catheterized in brachial, axillary or subclavian sites as the reference method [6]. Since the intraarterial blood pressure measurement is considered as an invasive method, in this study the patients were never solely catheterized with the purpose of NIBP device validation and there was not made any interfering within the patients medical intervention by SAADAT group.

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This study is conducted by random recruitment of 20 patients undertaken cardiac surgery in the ICU ward and operating room of Rajaei hospital in Tehran who were already catheterized in brachial artery. The measurement results of a patient due to the excessive motion and weak pressure signals were excluded. The whole validation procedure was performed under supervision of a highly experienced cardiovascular anesthesiologist.

A. Validation Procedure

In order to meet the mentioned requirements of the AAMI SP10, simultaneous measurements and comparisons between NIBP and IBP were carried on with the cuff and catheter placing both on the left arm. Time interval between each pair of measurements was set on 2 to 4 minutes. Additionally all the required principles for an accurate IBP reading such as the appropriate transducer leveling to the patient heart, zeroing and bubbles removing from the arterial line were fully maintained. Within the period of the measurements, the anesthetized patients were fully laid on the back with proper leveling between the IBP transducer and the patient's heart and the awake patients in the ICU wards were seated on the back with the heart leveled IBP transducer and the flexed arm. In order to reduce the disturbances effect on the measurements, the patients were advised not to talk and move. All the measured signals and data of the patients relating to the NIBP and IBP were stored via data collecting software which is written in visual C# by R&D department of the Saadat Co.

According to the AAMI, the target population must meet the specified requirements from different aspects such as size of the data base population, the arm size circumferences, pressure ranges and distributions. These AAMI requirements are defined more in detail in the Table 1 provided in the results section. In this study, 195 pairs of measurements were made on 19 patients with the age average of 54.89, 63.15% (12/19) male and 36.84% (7/19) female. Patients arm circumferences also met the AAMI criteria in which 10.52 % of the participants arm size was lower than 25 cm, 10.52 % greater than 35 cm and the rest of them remained between these outer limits. Moreover, the pressure ranges and distributions are also reported with more details in the Results section.

B. Data Analysis

According to the AAMI SP10, the mean ± SD differences between the test device readings and the reference method must be lower than 5 ± 8 mmHg for systolic, diastolic and map pressures [6]. It is also recommended to use all individual measurements in data analysis rather than using the average of the measurements for each subject [6]. The same procedure was used in this study and the results were analyzed with the Matlab version 7.11.0.584 software. The limits of agreements between the two methods were described by Bland-Altman plot which is recommended by the AAMI protocol to show the relationship between the two techniques [6].

III. RESULTS

Participants' pressure ranges for systolic, diastolic and map pressures were 82-181 mmHg, 47-103 mmHg and 67-127 mmHg respectively. Measurement database contains 17.44 % of systolic pressures bellow 100 mmHg, 15.9 % of diastolic pressures bellow 60 mmHg, 2.56 % of systolic pressures above 180 mmHg and 2.56 % of diastolic pressure above 100 mmHg. In this study the test device met the mentioned requirement of the AAMI with mean ± SD of -0.9 ± 6.95 for systolic, 2.57 ± 7.79 for diastolic and 3.89 ± 7.06 for map pressure. All the above database information is summarized in the validation results and AAMI requirements table (Table 1). Bland-Altman plot is used to present the discrepancies between the test device and the reference method for systolic, diastolic and map pressures in Fig. 1, Fig. 2 and Fig. 3 respectively. The y-axis is the difference between the test device and the reference method (in mmHg) and the x-axis is the average of the both techniques (in mmHg) [7]. The limits of agreements in the mentioned figures lie between mean ± 1.96 sd. As shown in the plots only a few of data points for systolic, diastolic and map pressures are scattered out of the limits of agreements.

TABLE 1. Validation Results and AAMI Requirements

Validation Results & AAMI Requirements		
Criteria	**Validation Results**	**The AAMI Requirements**
Subjects	19 with total 195 pairs of measurements	15 with at least total 150 pairs of measurements
Age Average	54.89 yrs old	-
Gender	Female: 36.84 % (7/19) Male: 63.15 % (12/19)	-
Arm Circumference	10.52 % < 25 cm 10.52 % > 35 cm The remainder b/w the above limits	10 % < 25 cm 10 % > 35 cm The remainder b/w the above limits
Pressure Range	82-181 mmHg systolic 47-103 mmHg diastolic 67-127 mmHg map	- - -
Pressure distribution	17.44 % below 100 mmHg systolic 15.9 % below 60 mmHg diastolic 2.56 % above 180 mmHg systolic 2.56 % above 100 mmHg diastolic	10 % below 100 mmHg systolic 10 % below 60 mmHg diastolic 10 % above 180 mmHg systolic 10 % above 100 mmHg diastolic
Mean ± SD	-0.9 ± 6.95 for systolic 2.57 ± 7.79 for diastolic 3.89 ± 7.06 for map	≤ 5 ± 8 mmHg

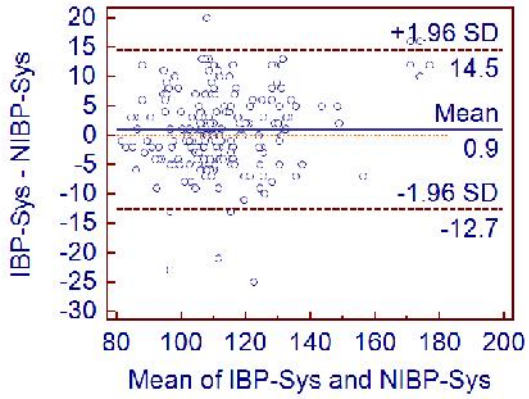

Figure 1. Systolic pressure Reference value minus Test value versus mean of Reference & Test values for 195 pairs of measurements (n=195) Limits of agreements (Mean ± 1.96 SD): (-12.7 to 14.5)

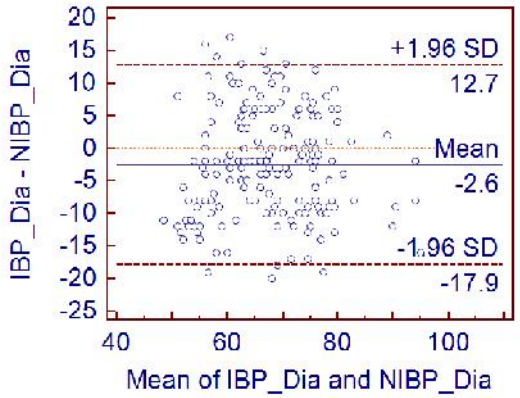

Figure 2. Diastolic pressure Reference value minus Test value versus mean of Reference & Test values for 195 pairs of measurements (n=195) Limits of agreements (Mean ± 1.96 SD): (-17.9 to 12.7)

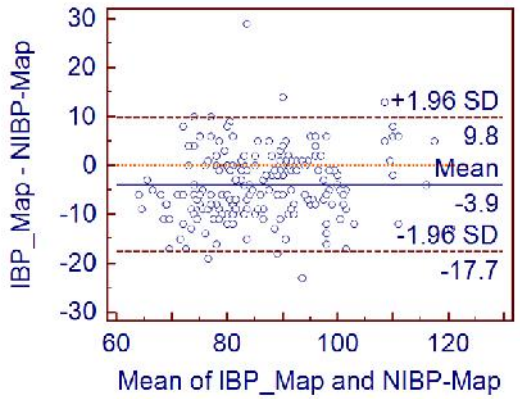

Figure 3. Map pressure Reference value minus Test value versus Mean of Reference & Test values for 195 pairs of measurements (n=195) Limits of agreements (Mean ± 1.96 SD): (-17.7 to 9.8)

IV. DISCUSSION

In present study, Saadat NIBP validation against IBP met the AAMI regulation based on the analysis done on the database of 19 patients. The limitation of this study is in the area of high blood pressure over 180 mmHg for systolic and over 100 mmHg for diastolic pressure. It should be noted that systolic/diastolic pressures over 180/100 mmHg (arterial hypertension) are considered as a chronic medical condition in which the necessary medical interventions should be applied immediately to overcome this emergency event and maintain the patient's clinical stability [1]. So the patients with this long-term medical condition (hypertension) letting us to do the whole measurement procedure are hardly available in the hospital. However, in case of device validation by comparing to the intra-arterial blood pressure measurements, the AAMI recommended that "the range of blood pressure and arm sizes should be as close as possible to that specified in 4.4.2.1" [6]. The requirements of 4.4.2.1 part of the AAMI are represented in the validation results and AAMI requirements table (Table 1). It is also reported in other studies that there are difficulties in finding the patients with extreme blood pressure [8]. Although the modified blood pressure ranges were used in their works, the evidence of their validation reports were accepted by the regulation committees [9-11]. Moreover, most of these studies validated the test device against the auscultatory method and observer readings. O'Brien et al demonstrate that some required protocols conditions such as the number of the subject database and the blood pressure ranges make the validation procedure difficult for the investigation centers to perform it and only a few of the tested devices met the protocol guidelines and could be recommended to use in clinical settings or research studies [12]. Despite the lack of published evidences of the reliability and accuracy of automated devices, Saadat team could successfully conduct the study according to the AAMI protocol requirements and publish the results.

V. CONCLUSION

The Saadat NIBP device fulfilled the AAMI validation requirements of automated oscillometric devices according to the analyzed results of the measurements and it is recommended to be used for clinical or research purposes.

REFERENCES

[1] T. G. Pickering, et al, "Recommendations for Blood Pressure Measurement in Humans and Experimental Animals: Part 1: Blood Pressure Measurement in Humans: A Statement for Professionals From the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research," *Hypertension*, vol. 45, pp. 142-161, Dec. 2004.

[2] A. Jones, and O. Pratt, "Physical principles of intra-arterial blood pressure measurement," *ATOTW 137*, pp. 1-8, Jun. 2009.

[3] The World Health Organization,"The world health report: 2002, reducing risks, promoting healthy life," *JAMA 288*, 1974.

[4] G. Drzewiecki, R. Hood, and H. Apple, "Theory of the oscillometric maximum and the systolic and diastolic detection ratios," *Annals of Biomedical Engineering*, vol. 22, pp. 88-96, 1994.

[5] E. O'Brien, B. Waeber, G. Parati, J. Staessen, and M.G. Myers, "Blood pressure measuring devices: recommendation of the European society of hypertension," *BMJ*, vol. 319, pp. 531-536, 2001.

[6] American National Standards Institute, Association for the Advancement of Medical Instrumentation, ANSI/AAMI SP10-2002, "American National Standard for electronic or automated sphygmomanometers," Arlington, AAMI, 2002.

[7] J. M. Bland, and D. G. Altman, "Statistical Methods for assessing agreement between two method of clinical measurement," pp. 307-310, 1986.

[8] R. A. Khawaja, R. Qureshi, A. H. Mansure, and M. E. Yahya, "Validation of Datascope Accutor Plus™ using British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) protocol guidelines," *Saudi Heart Association*, vol. 22, pp. 1-5, March 2010.

[9] A. Coleman, P. Freeman, S. Steel, and A.H. Sheenan, "Validation of the Omron 7051T BP monitoring device according to the BHS protocol," *Blood Pressure Monitoring*, vol. 11, pp. 27-32, 2006.

[10] R. Braam, C. De Maat, and T. Thien, "Accuracy of the Welch Allyn vital sign monitor52000 automatic blood pressure measuring device according to a modified BHS protocol," *Blood Pressure Monitoring*, vol. 7, pp. 185-189, 2002.

[11] A.C. Cuckson, A. Reinders, H. Shabeeh, and A.H. Sheenan, "Validation of the Microlife 3BTO – a oscillometric blood pressure monitoring device according to a modified BHS protocol," *Blood Pressure Monitoring*, vol. 7, pp. 319-324, 2002.

[12] E. O'Brien, et al, "The British Hypertension Society protocol for the evaluation of blood pressure measuring devices," *Hypertention*, vol. 11, pp. 43-62, 1993.

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