

Validation Study of the Dinamap Compact TS According to the International Protocol of European Society of Hypertension in Preschool Children in Ogbomoso, Nigeria

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DOI: <https://doi.org/10.52403/ijhsr.20220401>

ABSTRACT

Accurate blood pressure (BP) measurement is central to high-quality hypertension management. There is a lack of validated and approved oscillometric BP devices in clinical and epidemiological settings for paediatric age groups.

This study determined the accuracy of the Dinamap Compact TS in measuring the BP of preschool children in Ogbomosho by comparing the measurements obtained with the mercury sphygmomanometer in accordance with the International Protocol of the European Society of Hypertension (ESH-IP2). It also provided oscillometric BP reference values for preschool children.

The study was a cross-sectional survey of 700 children aged between 12 and 60 months from registered day-care centers, nursery and primary schools in Ogbomosho. Each participant underwent 7 same-arm sequential BP measurements by trained researchers alternatively using a mercury sphygmomanometer and the test device. The results were analysed according to the validation criteria of ESH-IP2.

Dinamap Compact TS satisfied the six criteria of Part 1 validation test and the two criteria of Part 2 validation test for SBP and DBP. There was a positive correlation between the 2 devices in terms of SBP ($r = 0.947$) and DBP ($r = 0.910$) readings. Using the Bland-Altman plots, nearly all readings (99.3% of SBP and 99.1% of DBP) of the 2 devices were within the limits of agreement, which was indicative of a high level of agreement between the BP devices. Gender-specific BP percentiles, which simultaneously accounted for age, height and height percentile were constructed.

It is recommended that BP of preschool children between the ages of 12 – 60 months could be measured using the Dinamap Compact TS and the developed BP charts should be used as references for easy interpretation and detection of elevated BP.

Keywords: Validation, Protocol, Hypertension, Children.

INTRODUCTION

Blood pressure (BP) measurement is an essential part of physical examinations in paediatric practice.(1-3) Accurate measurement of BP is essential to classify

individuals range of BP, to ascertain BP-related risk factors, and to guide further management.(4) The clinical procedure is the basis for the diagnosis, management, epidemiology and research of

hypertension.(5) Therefore, an accurate BP reading is a prerequisite for the reliable assessment of the level of BP regardless of which technique is used, though often the accuracy of measurement is taken for granted or ignored.(5)

While the mercury sphygmomanometer is still accepted as the 'gold standard' for routine clinical measurement, it suffers from two deficiencies: poor observer technique and problems due to poor maintenance of the devices.(6) This manual auscultatory technique has presented some difficulties when performed on children. It requires a quiet environment, which is not easy to maintain, and it can be difficult to detect the Korotkoff sounds accurately, especially in pre-school children.(7,8) In addition, mercury is a potent human neurotoxin. Due to the environmental concerns about the toxicity of mercury,(6,8) an international effort has developed to eliminate health-care sources of mercury – most importantly the mercury sphygmomanometer – and replace them with less toxic alternatives. There is concern regarding the accuracy of these alternative devices.(9)

There is no generally accepted alternative, the most widely advocated candidates are aneroid or oscillometric devices.(6) The aneroid device is the most popular alternative device for the auscultatory technique.(10) Aneroid sphygmomanometers have been found in practice to be frequently deficient, and are subject to the same deficiencies in observer technique as mercury devices.(6)

Therefore it is not strongly recommended, due to considerable variations in its accuracy, varying from 0 to 35%.(11) On the other hand, automatic oscillometric BP devices have gained increasing popularity and acceptance in the clinical field, as they are easy to use and do not need much observer expertise. As such, they can be used for BP measurements in children without observer errors.(6) The big disadvantage is that the oscillometric method is quite different from the

auscultatory method, and the correlation between the two is not always close.(10) Oscillometric devices have the advantages of eliminating observer error and mechanical drift, but it is suggested that the inherent limitations of the oscillometric method mean that it cannot become the gold standard for clinical measurement in individual patients.(6)The selection of a BP measuring device may be influenced by many factors, but a fundamental requirement must be that it gives accurate measurements.(12)

The British Hypertension Society (BHS)(13) and Association for the Advancement of Medical Instrument (AAMI)(14) have recommended that all automated oscillometric BP devices for measuring BP should be independently validated.(12,14) Despite widespread use of oscillometric devices, there is limited published evidence for their reliability and accuracy due to the complex validation protocols.(3,13,14) Out of many, only few studies(10,15–17)conducted on the subjects were according to the validation protocols.

Nevertheless, the trend is towards the use of oscillometric devices which are easier to use, eliminate digit preference and are safe.(18)Oscillometric devices have been recommended for BP measurements in infant and children for over a decade.(8,19)

Despite its advantages(20)over the conventional mercury sphygmomanometer, most researchers preferred the use of mercury sphygmomanometer in their studies (8,21,22) with few exceptions. (7,23) The most widely used of these devices are those manufactured under the name 'DINAMAP,' (24) which is the acronym for 'Device for Indirect Non-invasive Automatic Mean Arterial Pressure'. The Dinamap monitors have become widely used in paediatric care since their accuracy in reflecting direct arterial BP was reported in neonates, infants and children.(2) Most oscillometric devices are manufactured for adults, whose arteries are stiffer than children's arteries. Their accuracy and performance, therefore, must be verified using a mercury

sphygmomanometer as the gold standard in separate groups of children based on age, gender and height.(10)

The British Hypertension Society (BHS)(13) and the Association for the Advancement of Medical Instrumentation (AAMI)(14) set standard criteria for validating these devices against the mercury sphygmomanometer. The Working Group on BP Monitoring of the European Society of Hypertension (ESH)(12) updated the protocol, simplified the validation procedure without sacrificing accuracy.(10) In 2010, the protocol was revised and further simplified.(3) All these validation protocols, however, were confined to adults over the age of 25 years and were not applicable to children and adolescents.(10) No protocols have been specifically developed for device validation in children and experiences with validation studies in children are very limited.(10)

Several Dinamap models have been developed, each with an updated algorithm. Validation data have to be obtained separately for each model.(24,25) There is a lack of validated and approved oscillometric devices for use in clinical and epidemiological settings for paediatric age groups.(24) Thus, there is paucity of normative data on oscillometric BP measurements from other parts of the world (26–30) including in Nigerian children.(20–22) This study was done to address these knowledge gaps.

METHOD

This study was done in Ogbomosho North Local Government Area (OGBNLGA) of Oyo State, South Western Nigeria. It is one of the 33 Local Government Areas in the state with headquarters in the town of Ogbomosho.

Approval to conduct the study was given by the Ethical Review Committee of the LAUTECH Teaching Hospital (LTH), Ogbomosho, Oyo State Ministry of Education and Ministry of Women Affairs. Permission was obtained from the headmasters/headmistresses of the selected

schools, and the proprietors of the selected day-care Centres. A written informed consent was obtained from the parents or caregivers,

The study was a prospective, descriptive, cross-sectional survey carried out over a period of five months,

Apparently healthy children aged 1-5 years registered in day-care centres, nursery and primary schools (public and private) in OGBNLGA, who parental consent and school authority permission obtained were recruited for the study, those of them with gross deformity of lower limb and spine; on drug that could affect blood; suffered diarrhea within prior two weeks were excluded.

The final sample size was calculated to be 648, which will be four-fold the minimum sample size to double the accuracy at the fixed significance level.(31)

Multi-stage random sampling technique was employed to select schools/day-care centres and participants.

A validation procedure was performed on the Dinamap Compact TS Monitor based on the ESH-IP2(3) protocol modified by Lee *et al*(10) for children. Lee *et al*(10) modified ESH-IP2(3) protocol in their study with adoption of an aspect of BHS protocol(13) – determination of BP range using age-specific mean and standard deviation to define the criteria for the high, mean, and low BP ranges. The authors(10) derived the range of BPs in their study using a local study (32) due to deficiency of ESH-IP2(3) protocol in determining BP ranges in children. The researcher adopted the modified ESH-IP2(3) protocol in determining the participants' BP ranges using a local study(22) with similar age group. There were no available local reference data to determine the BP ranges in this age group.

Each participant underwent 9 same-arm sequential BP measurements alternating between mercury sphygmomanometer readings simultaneously taken by research assistants 1 and 2 (five readings) and the test device (four readings) taken by the

researcher. If the difference in readings by research assistant 1 and 2 was more than 4 mm Hg, the measurements were repeated. Intervals between measurements were between 30 seconds and 1 minute. The initial auscultatory reading was used to determine the participants' range of BPs by their mean, the initial reading taken with the test device was to make it familiar to the participants. The initial two readings were not used in the analysis. The results were analysed according to the validation criteria of ESH-IP2 and then the accuracy of the Dinamap Compact TS Monitor in children aged 1 to 5 years was assessed and compared with the requirements of the ESH-IP2.

Although the ESH-IP2 was originally limited to adults over the age of 25 years, it referred to selection of paediatric subjects. It recommended that larger samples should be analysed proportionally to the original 33-subject sample when the validation study for children and adolescents is planned, in accordance with ESH-IP2, as they have a

wide range of body size and blood pressure levels. The exact number of paediatric subjects, however, is not denoted on the ESH-IP2 procedure. Seven hundred children (proportional to the original 33-subject sample) were recruited, an average of 170 participants each from the following age groups: 12 to 23 months, 24 to 35 months, 36 to 47 months and 48 to 60 months.

To ensure a uniform distribution of participants' range of BPs, the BHS protocol recommended age-specific mean and standard deviation to define the criteria of the high, mean, and low BP ranges (high BP group, $>\text{mean} + 1 \text{ SD}$; mean BP group, $\text{mean} - 1 \text{ SD} < \text{BP} < \text{mean} + 1 \text{ SD}$; low BP group, $<\text{mean} - 1 \text{ SD}$ respectively). In addition, the number of subjects across a representative range, high and low BPs, should account for at least 17% (119 subject each in this study).

In this study, participants' ranges of BPs within each age group were derived from BP values for boys and girls with similar ages in mean (SD) blood pressure table for Nigerian children.

Table I : Means and SDs of blood pressures by sex, age among Nigerian children⁽²²⁾

	MALE			FEMALE		
	Mean(SD)	-1 SD Low	+1 SD High	Mean(SD)	-1 SD Low	+1 SD High
SBP(mm Hg)						
12 - 23	85.5 (7.1)	78.4	92.6	85.5 (7.9)	77.6	93.4
24 - 35	86.6 (9.0)	79.6	97.6	86.5 (8.9)	77.6	95.4
36 - 47	89.5 (9.2)	80.3	98.7	87.9 (9.0)	78.9	96.9
48 - 60	90.6 (9.3)	87.3	99.9	90.7 (8.7)	82.0	99.4
DBP(mmHg)						
12 - 23	31.4(23.3)	8.1	54.7	38.2 (22.2)	16.0	60.4
24 - 35	37.1(19.9)	17.1	57.0	41.1 (17.1)	24.0	58.2
36 - 47	41.2(17.8)	33.4	59.0	39.9 (19.9)	20.0	59.8
48 - 60	44.1(18.7)	35.4	62.8	42.7 (18.9)	23.8	61.6

1. Validation measurements

The BP measurements were taken in the morning hours between 8.00 am and 11.00am before the pupils went on break. BPs were measured after 5 minutes of rest with Accoson's mercury sphygmomanometer, using the auscultatory method. The BP was measured with the participants sitting with the back supported, feet on the floor and right arm supported, the cuff bladder length covering 80% to 100% of the arm circumference.(8)

Research assistants 1 and 2 were blind to each other's manometer recordings.

The BPs were measured simultaneously by the two research assistant with the antecubital fossa at heart level (8) using Dual ear-pieces Classic II Littman's Paediatric stethoscope to auscultate the Korotkoff sounds. The open bell of the stethoscope was placed over the brachial artery pulse, proximal and medial to the antecubital fossa, and below the lower edge of the cuff (ie ≈ 2 cm above the antecubital

fossa).SBP was determined by the onset of the “tapping” Korotkoff sounds (K1) and DBP by the fifth Korotkoff sound (K5), “the disappearance of Korotkoff sounds.”(8) All eligible participants were in the same room to witness the procedure in order to reduce anxiety.

Critikon Dinamap Compact TS Monitor device was operated according to the manufacturer’s specification. Measurement was done as recommended in the 7th Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-7)(33) with the subjects sitting quietly and the right arm on a table at the level of the heart.

An appropriately sized cuff according to the recommended age group covering about two-thirds of the upper arm with the lower border not less than 2.5 cm from the cubital fossa, was applied after restricting clothing had been removed.(8) The monitor was at the level of the cuff. After the initial two auscultatory readings to determine the range of BP by their mean, one reading was taken with the test device to make it familiar to the child. The initial three readings were not used in the analysis. Seven same-arm sequential measurements were then taken, alternating between mercury sphygmomanometer readings simultaneously taken by research assistants 1 and 2 (four readings) and the test device (three readings). If the difference in readings by research assistant 1 and 2 was more than 4 mm Hg, the measurements were repeated. Intervals between measurements were between 30 seconds (to avoid venous congestion) and 1 minute (to minimise variability).

The participants each underwent nine sequential BP measurements as follows:

a) Entry blood pressure A (BPA) with mercury sphygmomanometer by research assistants 1 and 2 with the average of the measurements documented. This is to allocate the participants into the appropriate BP range groups. Then entry blood pressure

B (BPB) with test device by the researcher. This is alternated between the research assistant and the researcher.

The readings from the test device were compared with the mean of the two measurements taken by research assistant 1 and 2 immediately preceding and following the test device measurement that is: BP2 was compared with BP1 and BP3, BP4 with BP3 and BP5, BP6 with BP5 and BP7. The smaller absolute value of the two differences was taken. Thus, for each child, three pairs of BP comparisons were obtained. For the accuracy requirements, the percentages of BP pairs whose differences fell within 5, 10, 15 and more than 15 mm Hg (corresponding to A, B, C, and D, respectively) were calculated for the device and compared with the requirements of the ESH-IP2(3) for all the participants.

The first requirements for passing were that: two out of three criteria or all of three criteria should be satisfied

two out of three criteria:

- 1) 73% of BP differences that fell within 5mm Hg for A,
- 2) 87% of BP differences that fell within 10mm Hg for B,
- 3) 96% of BP differences that fell within 15mm Hg for C

or **all of three criteria:**

- 1) 65% of BP differences that fell within 5mm Hg for A,
- 2) 81% of BP differences that fell within 10mm Hg for B
- 3) 93% of BP differences that fell within 15 mm Hg for C.

The second requirement for passing were:

- 1) participants with more than two As of the three BP pairs (that is having differences within 5 mm Hg) had to be over 73% of the participants.
- 2) participants with zero As of three BP pairs (that is having differences within 5 mm Hg) had to be less than 9% of the participants.

The third requirement was the mean \pm SD of the BP differences (test device minus mercury auscultatory readings). This is to check whether those differences

satisfied the requirement of AAMI, which should be less than 5 ± 8 mm Hg.

Data Analysis

Data collected on the proforma were entered into a master sheet using numerical codes. Data entry and analysis was carried out using the IBM®SPSS version 20.0 (IBM Corporation, Virginia, U.S.A.) software package of a micro-computer.

RESULT

Demographic Characteristics

There were 700 participants, comprising children from private

nursery/primary schools (n = 391; 55.9%), Crèches (n = 117; 16.7%) and public primary schools (n = 192; 27.4%). There were 343 (49%) males and 357 (51%) females giving a male to female ratio of 1:1.

Figure 1 shows Bland-Altman plots presenting differences and average of SBP between Dinamap compact TS and standard mercury sphygmomanometer readings for all age groups. Largely there was a very high level of agreement between readings of the tested device and standard device. Only 5 out of the 700 readings were outside the limits of agreement.

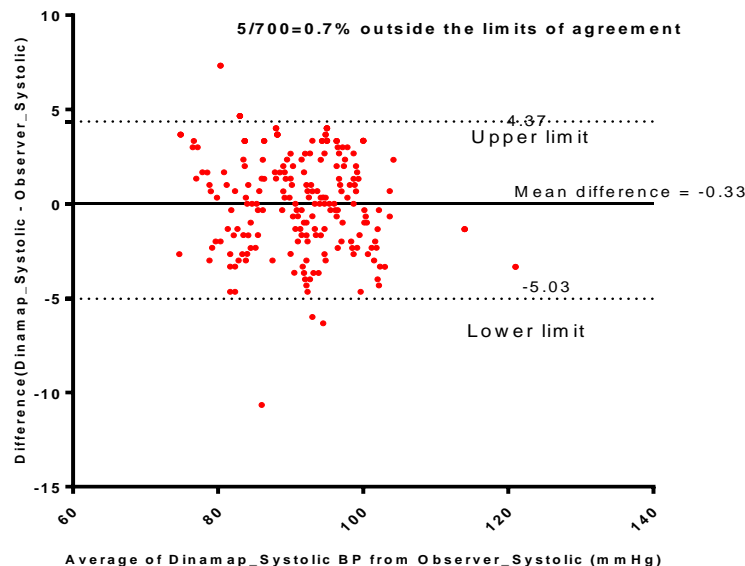


Figure 1: Bland-Altman plots presenting differences and average of systolic blood pressure between the Dinamap compact TS and standard mercury sphygmomanometer readings for all age groups

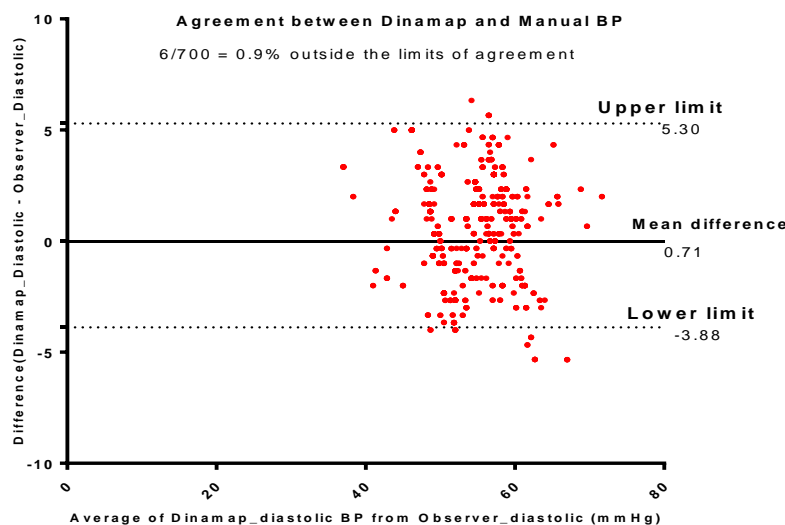


Figure 2: Bland-Altman plots presenting differences and average of diastolic blood pressure between Dinamap Compact TS and standard mercury sphygmomanometer readings for all age groups

Figure 2 shows Bland-Altman plots presenting differences and average of diastolic blood pressure between the Dinamap Compact TS and standard mercury sphygmomanometer readings for all age groups. Largely there was a very high level of agreement between readings of the tested device and standard device. Only 6 out of the 700 readings were outside the limits of agreement.

Figure 3 shows the correlational graph of mean and 95% Confidence intervals of systolic blood pressure from Dinamap Compact TS by age for all subjects. There was a gradual increase in systolic blood pressure with age. The expression relating the mean SBP and the age studied was $y = 82.07 + 0.23 * x$, where x = age in months.

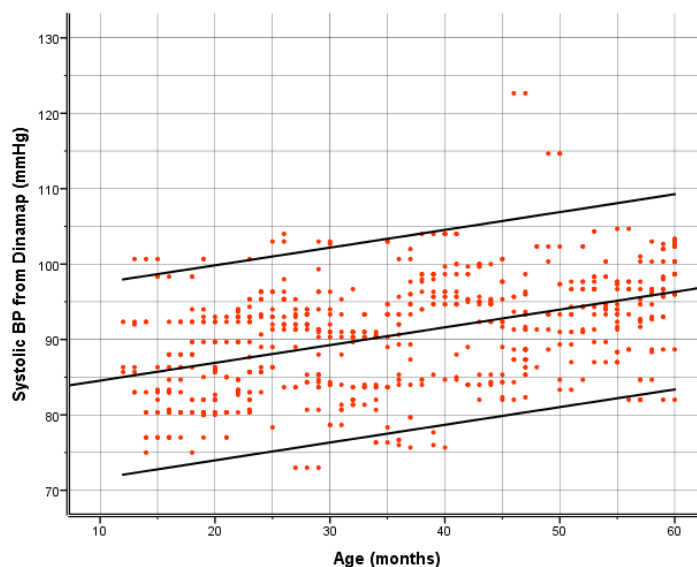


Figure 3: Correlational graph of mean and 95% confidence intervals of systolic blood pressure by age for all subjects

Validation results

The validation criteria of Part 1 and Part 2 of the ESH-IP2 modified for the number of participants and the results of the validation analysis are presented in Table II. According to the ESH-IP2 protocol, in the present study, the SBP difference between Dinamap Compact TS and mercury

sphygmomanometer were 94.6%, 99.9% and 100% within 5, 10, and 15 mm Hg, respectively while DBP differences were 93.1%, 99.9% and 100% within 5, 10, and 15 mm Hg, respectively. These results fulfilled the AAMI criterion of $\text{mean} \pm \text{SD}$ below 5 ± 8 mm Hg for both systolic and diastolic BP.

Table II: Results of the Validation analysis of Blood Pressure Readings (n =2100)

PART 1	≤ 5mm Hg	≤ 10mm Hg	≤ 15mm Hg	Grade 1	Mean (mm Hg)	SD (mm Hg)
Pass Requirements						
Two of Three criteria	1533 (73%)	1827 (87%)	2016 (96%)			
All of the three criteria	1365 (65%)	1701 (81%)	1953 (93%)			
Achieved						
SBP	1986 (94.6%)	2099 (99.9%)	2100 (100%)	PASS	0.36	3.14
DBP	1955 (93.1%)	2098 (99.9%)	2100 (100%)	PASS	- 0.50	3.47

With regards to the Part 2 criteria of ESH-IP2; in this study, the test device passed the two criteria for SBP and DBP (Table III). Six hundred and ninety two (692) 98.8% of the participants had more

than two 'As' out of three SBP pairs difference (that is having differences within 5 mm Hg) while 97.3% of the participants had more than two 'As' out of three DBP pairs difference (that is having differences

within 5 mm Hg). None of the participants (0%) had zero 'As' out of the three SBP and DBP pairs difference.

In conclusion, the test device passed the grade 1 and AAMI criteria, it also passed the grades 2 and 3 for the validation test.

Table III: Results of the Validation Analysis of Individual Children (n=700)

PART 2	2/3	0/3	Grade 2	Grade 3
	≤5 mm Hg	≤5 mm Hg		
Pass Requirements	511 (≥ 73%)	63 (≥ 9%)		
Achieved				
SBP	692 (98.8%)	0 (0%)	PASS	PASS
DBP	681 (97.3%)	0 (0%)	PASS	PASS

The null hypothesis is rejected and the alternate is accepted, thus the oscillometric BP device (Dinamap Compact TS) can accurately measure BP in preschool children and can be validated and be tested for reliability in preschool children.

This study determined the accuracy of an oscillometric BP device, Dinamap Compact TS, in preschool children aged 12 - 60 months in OGBNLGA. It also demonstrated a strong positive correlation between BP values obtained using the Dinamap Compact TS and the mercury sphygmomanometer. Thus Dinamap Compact TS has been validated and its reliability has been tested in preschool children. This is important because no protocols have been specifically developed for device validation in preschool children and experiences with validation studies in children are very limited.(34,35) The study also proposed a normative oscillometric BP values in Nigerian children aged 12 to 60 months which may be useful in clinical and epidemiological settings.

In the present study, the Dinamap Compact TS demonstrated its clinically acceptable accuracy in SBP and DBP measurement within the accepted levels of the validation criteria of the ESH-IP2, (3) and therefore passed the validation criteria of the ESH-IP2 in preschool children. The test device satisfied the three requirements to assess BP device accuracy. Hence, Dinamap Compact TS passed Part 1 and Part 2 criteria of the validation test for both SBP and DBP according to ESH-IP2(3) protocol guidelines. In addition, the test

device passed the AAMI criteria(14) for both SBP and DBP.

Most data from previous reports except Wong *et al.*,(34) were obtained from different validation protocols that had undergone modifications over years, therefore, it may be difficult to directly compare and contrast the results of the present study with previous ones as different validation protocols were used.

DISCUSSION

The findings of this study may be comparable to those from other studies of simultaneous measurements using different devices, different protocols, similar age groups and clinical setups. (34–40)The BP difference between Dinamap Compact TS and mercury sphygmomanometer were 94.6%, 99.9% and 100% for SBP and 93.1%, 99.9% and 100% for DBP within 5, 10, and 15 mm Hg, respectively in this study. These results are similar to the study in Canada(39) and China. The present study and the two other studies(34,39) fulfilled the ESH-IP2 criteria for validation but the current study has a higher percentage differences in SBP and DBP readings. In contrast, Wong *et al.*(34) reported two other BP devices (Dinamap Procure-120 and Welch-Allyn Vital Signs) in same study that failed ESH-IP2 validation criteria. These may be attributed to the larger sample size proportionally allocated to the preschool age children in the current study which may result in greater study power and sensitivity. (41)

In the current study, the device met the testing requirements of the AAMI which

is similar to previous studies by Ling *et al* in Houston,(38) Dong *et al* in China(37), Narogan *et al* in Moscow,(35) Alpert in Memphis (36) and Mattu *et al* in Canada .(39) The validation protocol used by the present study incorporated the modified AAMI protocol/criteria as part of the validation procedure which may explain the similarities in result outcomes. The current study has a better mean difference and standard deviation than the previous reports (34,38,39,42) but similar to values recorded in Italy(40) and China. (37) This can be attributed to the large sample size which may have resulted to greater study accuracy.(41,43)

Another important observation in the present study is the strongly positive correlation between the SBP and DBP measurements of the Dinamap monitor and the manual sphygmomanometer. There was a very high level of agreement between SBP and DBP readings of the Dinamap monitor and those of the standard manual sphygmomanometer across the age groups and genders++studied. This is consistent with the findings of other researchers (7,35,38,44) but contrary to other reports (34,42). The strong correlation observed in this study may be due to increased accuracy of the two research assistants' measurements, proper selection of cuff sizes depending on the mid-arm circumference and strict usage of K5.(38). In addition, strict adherence to the validation procedure in the current study may also be attributed to the different reports recorded in UK(42) and Chinese(34) study.

The study had its limitations. The ESH-IP2 protocol was mainly designed for adults; no protocols have been specifically developed for the device validation in children, and experiences with validation studies in children are very limited. The potential effect of adapting the adult protocol for use remains unexplored.

Acknowledgement: None

Conflict of Interest: None

Source of Funding: None

Ethical Approval: Approved

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How to cite this article: Alabi Victor Olukayode, Onigbinde Michael Olaniyan, Ogunkunle Oluwatoyin et.al. Validation study of the Dinamap compact TS according to the international protocol of European society of hypertension in preschool children in Ogbomoso, Nigeria. *Int J Health Sci Res.* 2022; 12(4):1-11. DOI: <https://doi.org/10.52403/ijhsr.20220401>
