Author’s response to reviews

Title: Validation of Omron HBP-1300 Professional Blood Pressure Monitor based on Auscultation in Children and Adults

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Dear editor and reviewers:

Thank you for your letter and for the reviewers’ comments concerning our manuscript entitled “Validation of Omron HBP-1300 Professional Blood Pressure Monitor based on Auscultation in Children and Adults” (BCAR-D-15-00089). Those comments are all valuable and very helpful for revising and improving our paper. The main corrections in the paper and the responds to the reviewers’ comments are as followings:
Responds to the reviewers:

Reviewer #1: This paper describes a validation study using the AAMI protocol of the OMRON HBP-1300 monitor. The methods are well describes but there is some confusion around cut off points: page 7 why was the validation stopped if observers could not agree on diastolic but not systolic readings?

Answer 1: In fact both diastolic and systolic blood pressure readings should agree between the observers. In the manuscript diastolic and systolic were described separately. In order not to mislead the readers the content has been revised as “Studies were stopped or rejected if subjects had arrhythmia, could not sit still for the study, or avoid strenuous exercise. Studies were also excluded if the average systolic readings differed by >12 mmHg or the diastolic reading varied by >8 mmHg after several attempts.”

Why were patients excluded if the difference between observers was >10 mmHg systolic and >8 mmHg diastolic rather than the 10 and 5 mmHg described in the protocol.

Answer 2: The AAMI standard states that 100% of simultaneous measurements should agree to within ±10 mmHg and ≥90% should agree to within ±5 mmHg for both SBP and DBP. That means 10% participants were permitted not agreeing to within ±5 mmHg for both SBP and DBP. If the variation over 8mmHg for DBP, the fluctuation of blood pressure in the following test would be larger than others. That’s the reason the patients were excluded if the difference between observers was >10 mmHg systolic and >8 mmHg diastolic. Although doing that this study was exactly meet the AAMI standard in fact.

It would be useful to know what cuff sizes the children had and what size the adults.

Answer 3: There were 5 size cuffs provided to Omron HBP-1300 Professional Blood Pressure Monitor in the market. The cuff range, cuff size labels, and the numbers of children and adults in each category were presented in table 2. These contents and an additional table2 had been revised in the revised manuscript.

My main concern is that it did not include >10% of readings >160 mmHg demanded by the protocol but instead included 8.2%. This means that there is a concern that the device may not be accurate for higher systolic readings.

Answer 4: Thank you for your question. The request of participants with an initial SBP > 160 mmHg has been changed from ≥10% in ANSI/AAMI/ISO81060-2:2009 to ≥5% in ANSI/AAMI/ISO81060-2:2013. So 8.2% of readings >160 mmHg is enough in our test.

Reviewer #2: This is a nicely prepared work. However, there are some revisions which should be done.

1. The validation protocol used should be defined exactly, e.g. "ANSI/AAMI/ISO81060-2:2013" and referenced.

Answer 1: Thank you for your suggestions. And we have defined the protocol exactly as "ANSI/AAMI/ISO81060-2:2013" and the reference (International standard ISO 81060-2 Non-invasive sphygmomanometers-part2 Clinical investigation of automated measurement type. ANSI/AAMI/ISO81060-2:2013) has been added in the manuscript just like you suggested.

2. Methods: Introduction of the AAMI standard: This section should be shortened. It is not necessary to give information about the requirements of the protocol.

Answer 2: Thank you for your good suggestion. The details of the protocol have been shorted in the manuscript.

3. Methods: Test device: It would be interesting how many cuff sizes are available for the device. According to the protocol "ANSI/AAMI/ISO81060-2:2013" all cuff sizes have to be tested in a defined number of participants depending on the number of cuff sizes.

Answer 3: There were 5 size cuffs provided to Omron HBP-1300 Professional Blood Pressure Monitor in the market. The cuff range, cuff size labels, and the numbers of children and adults in each category were presented in table 2. These contents and an additional table2 had been revised in the revised manuscript.

4. Methods: Introduction of the AAMI standard: "The AAMI standard provides two methods for accuracy determination…". According to ISO 81060-2: 2013 both methods (criterion 1 and 2) have to be used.

Answer 4: According to ISO 81060-2: 2013 the Criterion1 uses the 255 individual test -REFERENCE differences to determine the performance of the SPHYGMOMANOMETER – UNDER - TEST. As a result, the calculated standard deviation, sn (or precision) will reflect both intra-subject and inter-subject variability. However, the allowable standard deviation is constant even when the mean of difference, mean of n (or bias) is large. Criterion uses the average of the differences from each subject, so the calculated sm reflects only inter subject variability, and a large intra – subject variability can still pass this method. Criterion 2 attempts to prevent that by reducing the allowable sn as n increases, (sn=8.00mmHg versus sm=6.95mmHg), thus addressing both bias and inter-subject precision. In this manuscript both the criterions were used to test the validation of this sphygmomanometer and it has passed the request of both the criterions successfully. And this content has been added as a part of the discussion in our manuscript.

5. Methods: Protocol: Results should not be mentioned in this section but in the results e.g. "All SBP or DBP values of the observers…" and "The data analysis documents that the device…."


Answer 5: thank you for your review opinion and the protocol has been revised as you suggested, the content of the result has been cut from the protocol and as to the part of result. Just like the protocol defined in ANSI/AAMI/ISO81060-2:2013 was used in this study. The device should be documented to have passed ANSI/AAMI/ISO81060-2:2013 request through the data analysis.

6. Methods: BP measurements: Which method was used, same arm sequential? This should be mentioned.

Answer 6: Thank you for your suggestion and the method of BP measurement has been described in detail in the manuscript just like this: “The observers measured the circumference at the midpoint of the arm and selected an appropriate cuff, the width of which was as close as possible to 40% of the arm circumference. The cuff tubing had a three-way stopcock inserted to alternate the manual auscultatory readings. After each subject rested for at least 15 minutes, BP was measured on the left upper arm at the level of the heart and the lower arm passively supported. The interfacing two measurements were separated by at least 1 minute intervals. Heart rate was recorded in beats/minute at each visit. Then the button of start was pressed and the measurements started automatically.”

7. Results: According to the description of the test device there are more cuff sizes available and each cuff size has to be tested in a certain number of participants, which depends on the number of different sizes. How many cuff sizes are available and how many participants have been tested in each size? This should be mentioned in detail.

Answer 7: Thanks, you are quite right, there are 5 cuff sizes available and each cuff size had been tested. The numbers of participants tested of different sizes has been added in table2 in the manuscript like the following

<table>
<thead>
<tr>
<th>Cuff range (cm)</th>
<th>Cuff Size label</th>
<th>Need 85/2n(numbers of Cuff sizes) or 85/10=9</th>
<th>Numbers in this study</th>
</tr>
</thead>
<tbody>
<tr>
<td>R 12-18</td>
<td>SS</td>
<td>9</td>
<td>22</td>
</tr>
<tr>
<td>R 17-22</td>
<td>S</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>M 22-32</td>
<td>M</td>
<td>9</td>
<td>25</td>
</tr>
<tr>
<td>L 32-42</td>
<td>L</td>
<td>9</td>
<td>18</td>
</tr>
<tr>
<td>XL 42-50</td>
<td>XL</td>
<td>9</td>
<td>9</td>
</tr>
</tbody>
</table>

8. Results: The mean ± SD of the difference between the two observers should be mentioned for SBP and DBP, respectively.

Answer 8: Thanks for your suggestion, and the content of this part of “The average difference between observers and the device by the AAMI method 2 was 1.4 ± 3.2 mmHg for SBP and 1.0
± 3.9 mmHg for DBP, which met this guideline. ” was in the error statistics of the results of the manuscript.

9. Results: Page 8, line 23: There is an error in the sentence "The initial DBP was <60 mmHg…, and 100-160 mmHg in 53 participants…". It should probably be "…, and ≥85 mmHg in 53 participants…".

Answer 9: You are quite right. The sentence has been corrected as “The initial DBP was <60 mmHg in 23 participants (27.1%), >100 in nine participants (10.6%), and ≥85 mmHg in 53 participants (62.4%).” 100-160 mmHg is for SBP.

10. Limitations: According to ANSI/AAMI/ISO81060-2:2013 ≥5% should have an initial SBP > 160 mmHg.

Answer 10: You are quite right that according to ANSI/AAMI/ISO81060-2:2013 ≥5% have an initial SBP > 160 mmHg is enough. The limitation has been corrected.

11. Table 1: The number of patients tested with the cuff sizes available should be listed (see Revision 7)

Answer 11: Thanks, you are quite right, there are 5 cuff sizes available and each cuff size had been tested. The numbers of participants tested of different sizes has been added in table2 in the manuscript like the following

12. Figures are missing in this pdf.

Answer 12: Thank you for your reminding, and I’ll upload the figures again when the revision was uploaded.

Figure 1 Agreement between the test and reference methods for systolic pressure.

Figure 2 Agreement between the test and reference methods for diastolic pressure.

Editorial Requests

Please note that all submissions to BMC Cardiovascular Disorders must comply with our editorial policies. Please read the following information and revise your manuscript as necessary you’re your manuscript does not adhere to our editorial requirements this will cause a delay whilst the issue is addressed. Failure to adhere to our policies may result in rejection of your manuscript.
Ethics:

If your study involves humans, human data or animals, then your article should contain an ethics statement which includes the name of the committee that approved your study.

If ethics was not required for your study, then this should be clearly stated and a rationale provided.

Answer: the ethics statement: Written informed consent was obtained from each participant and/or their parents or guardians. The study protocol was approved by the Institutional Review Boards and Ethics Committees of Capital Institute of Pediatrics, China. This content was after the statistic method in the manuscript.

Consent:

If your article is a prospective study involving human participants then your article should include a statement detailing consent for participation.

If individual clinical data is presented in your article, then you must clarify whether consent for publication of these data was obtained.

Answer: Written informed consent was obtained from each participant and/or their parents or guardians. And no individual clinical data was presented in our article.

Availability of supporting data:

BioMed Central strongly encourages all data sets on which the conclusions of the paper rely be either deposited in publicly available repositories (where available and appropriate) or presented in the main papers or additional supporting files, in machine-readable format whenever possible. Authors must include an Availability of Data and Materials section in their article detailing where the data supporting their findings can be found. The Accession Numbers of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript must be provided and include the corresponding database name.

Answer: The database has been uploaded as an additional supporting file in machine-readable format.

Authors Contributions:

Your 'Authors Contributions' section must detail the individual contribution for each individual author listed on your manuscript.
Answer: The authors' contributions of ML, MJ and GP have made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data; ZD and PY have been involved in drafting the manuscript or revising it critically for important intellectual content; DW, WQ and LH have given final approval of the version to be published has been added.