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Evaluation of oscillometric blood pressure measurement devices available for online sale

Avaliação dos dispositivos oscilométricos de medida de pressão arterial disponíveis para comercialização on-line

Evaluación de los aparatos oscilométricos de medición de la presión sanguínea disponibles para comercialización en línea

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ABSTRACT

Objectives: to characterize oscillometric blood pressure measurement devices for sale in the virtual market and identify which ones have undergone a validation study. **Methods**: this was a cross-sectional study. The search for devices for sale was conducted on websites, and the sample was composed of 137 devices obtained from 644 ads. We conducted a bibliographic survey in five databases and web pages enlisting devices submitted for validation. The Kolmogorov-Smirnov test was used to check data distribution, followed by Mann-Whitney and Kruskal-Wallis tests for comparisons, using the SAS 9.4 program. **Results**: only 16.7% of the devices were validated. The home devices ranged from USD 10.57 to USD 275.67. Only 102 ads informed the cuff size, with different nomenclatures. **Conclusions**: most ads contained non-validated devices, which were cheaper. We identified some ads falsely informing validation. **Descriptors:** Blood Pressure; Blood Pressure Determination; Blood Pressure Monitors; Oscillometry; Validation Studies.

RESUMO

Objetivos: caracterizar os dispositivos oscilométricos de medida da pressão arterial à venda no mercado virtual e identificar quais passaram por estudo de validação. **Métodos:** trata-se de um estudo transversal. A busca dos aparelhos à venda foi realizada em páginas da *internet*, e a amostra foi composta por 137 aparelhos, obtidos em 644 anúncios. Foi realizado levantamento bibliográfico em cinco bases de dados e consultadas páginas da *internet* que registram aparelhos submetidos à validação. Utilizaram-se os testes Kolmogorov-Smirnov para verificação da distribuição dos dados, seguidos de Mann-Whitney e Kruskal-Wallis para comparações, por meio do programa SAS 9.4. **Resultados:** somente 16,7% dos dispositivos eram validados. Os aparelhos domiciliares apresentaram variação de R$ 58,70 a R$ 1.531. Apenas 102 anúncios informaram as dimensões da braçadeira, com nomenclaturas diferentes. **Conclusões:** a maioria dos anúncios continha aparelhos não validados, que eram mais baratos. Foram identificados anúncios com informações falsas sobre validação.
Descritores: Pressão Sanguínea; Determinação da Pressão Arterial; Monitores de Pressão Arterial; Oscilometria; Estudos de Validação.

RESUMEN

Objetivos: caracterizar aparatos oscilométricos de medición de la presión sanguínea a la venta en el mercado virtual e identificar cuales pasaron por estudio de validación. **Métodos:** discorre de un estudio transversal. La búsqueda de equipos a la venta fue realizada en páginas de *internet*, y la muestra fue composta por 137 equipos, obtenidos en 644 anuncios. Realizado levantamiento bibliográfico en cinco bases de datos y consultadas páginas de *internet* que registran equipos sometidos a validación. Utilizadas las pruebas Kolmogorov-Smirnov para verificación de la distribución de los datos, seguidos de Mann-Whitney y Kruskal-Wallis para comparaciones, mediante el programa SAS 9.4. **Resultados:** solamente 16,7% de los aparatos eran validados. Equipos domiciliares presentaron variancia de R$ 58,70 a R$ 1.531. Solo 102 anuncios informaron las dimensiones del brazalete, con nomenclaturas diferentes. **Conclusiones:** la mayoría de los anuncios contenía equipos no validados, que eran más baratos. Fueron identificados anuncios con informaciones falsas sobre validación.
Descriptores: Presión Sanguínea; Determinación de la Presión Sanguínea; Monitores de Presión Sanguínea; Oscilometría; Estudios de Validación.

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INTRODUCTION

Indirect blood pressure (BP) measurement is a non-invasive, simple, easy, and safe procedure performed at home or in health care facilities. It is one way to diagnose systemic arterial hypertension (SAH), considered one of the most critical risk factors for cardiovascular diseases[1].

Oscillometric and auscultatory methods can do this measurement. The oscillometric measurement is calculated by detecting variations in pressure oscillations by the movement of the arterial wall under the cuff[2]. It is important to emphasize that, among other indications, oscillometric devices are indicated for self-measurement of BP and are essential for performing home blood pressure monitoring (HBPM), a method that has been gaining prominence in recent years due to its practicality and efficiency in pressure control by hypertensive patients[3].

Several brands use different algorithms to perform BP calculations[4]; until now, these sequences have no standardization. Therefore, validation is the only way to ensure the minimum reliability of these devices[2]. Over 30 years, many renowned international organizations have created and improved validation protocols[5].

The measurement of BP has been recognized as one of the most relevant healthcare procedures. However, its accuracy is a frequent problem in clinical practice, considered a patient safety issue and a public health problem[6], since when non-validated devices are used, the SAH control might be based on inaccurate values, which can contribute to erroneous decisions by the healthcare team, with severe clinical consequences[7].

Since many brands and models have not undergone validation studies, the popularization of automatic devices is a worrisome factor. Considering the ease of purchase over the Internet, we ask ourselves which automatic sphygmomanometers available for commercialization have passed a validation study. The importance of performing such research ensures that the final consumer will not be harmed by using devices that may provide unreliable BP values.

OBJECTIVES

To characterize the oscillometric devices to measure BP for sale on the virtual market and identify which ones have undergone a validation study.

METHODS

Ethical aspects

Since the study does not involve human subjects, there was no need for ethical review. All data from the devices disclosed are available on the Internet and are freely accessible.

Design, period, and place of study

The study is a cross-sectional, descriptive, quantitative study, guided by the Strengthening the Reporting of Observational Studies in Epidemiology tool (STROBE). The research was conducted on Internet sales sites from June to October 2020. Given the multiplicity of sites available for oscillometric devices, we consulted the Top Ecommerce Ranking Reports list (link:https://ecommercebrasil.rankings.netquest.digital/#/global-ranking). This list is updated monthly and represents the 100 sites with the highest number of visitations and online purchases in Brazil. By examining the list's ranking between January and April 2020, we analyzed the sites that remained at least once among the top ten with the highest number of sales in Brazil and had the BP oscillometric devices as one of their sales categories. Fourteen sites were selected for data gathering; from then, we observed repeated information already collected, exceeding the sample size.

Sample; criteria of inclusion and exclusion

We consulted 876 ads for oscillometric devices available for sale on the Internet. Out of these, 222 ads were excluded for not presenting a brand and/or model, and ten because they were ambulatory blood pressure monitoring (ABPM) devices. The final sample was composed of 137 different devices, from 58 brands, obtained from the 644 ads.

Our consultation considered advertisements for oscillometric devices for BP self-measurement and clinical use, automatic or semi-automatic. Advertisements from international sites were consulted when they could deliver in Brazil. Ads that did not display the device brand and/or model and ABPM devices were excluded. A pilot study was conducted in March and April 2020 to define the sample size and test the data collection spreadsheet. Utilizing sales in March, we collected data related to 32 devices on sites occupying positions 99 and 100 on the Top Ecommerce Ranking Reports.

The sample size calculation estimated the proportion of devices submitted to the validation study, considering an infinite population[8-9]. Through the pilot sample, it was obtained a proportion *p* equal to 0.0938; furthermore, a sampling error of 5% and a significance level of 5% was assumed, which resulted in a minimum sample size of 131 devices.

Study protocol

Data collection was divided into two stages. In the first, the search for oscillometric devices was conducted in the determined sites between April and June 2020. The variables collected, entered directly into Microsoft Excel spreadsheets, were the brand, model, place of application (arm or wrist), mode of operation (automatic, semi-automatic), type of device (home or clinical), size of available cuffs, indicated brachial circumference (BC)/wrist, price, information on validation approval, information about recommendations by scientific society, and information on cardiac arrhythmia detection.

In the second stage, carried out from June to October 2020, the websites Dabl® EducationalTrust (DABL) [www.dableducational.org], MEdical Device Assessment and VALidation (MEDAVAL) [www.medaval.org] and STRIDE BP (STRIDE) [www.stridebp.org] were consulted, to search for validation studies of the collected devices brands and models. We want to point out that these associations do not always recommend the listed devices, but the criterion employed was the device's approval in a validation study, which should have been published as a complete article.

Then, with the same objective, we conducted a bibliographic survey in the Latin American and Caribbean Literature on Health Sciences (LILACS), Publisher Medline (PubMed), SciVerse Scopus (Scopus), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science, and Excerpta Medica Database (EMBASE) databases. To identify the published literature, we used individual search strategies in each electronic database to search each device found separately. The descriptors used were "blood pressure", "blood pressure determination", "blood pressure monitors", and their synonyms, all in English. Those devices that used internationally recognized validation protocols were validated, with results published in full articles. Devices registered on the DABL, MEDAVAL, or STRIDE websites, which had equivalence statements certified by these associations, were considered equivalent devices[7].

Analysis of results and statistics

A descriptive and inferential analysis of the data was performed using the Kolmogorov-Smirnov test to verify data distribution, followed by the Mann-Whitney and Kruskal-Wallis tests for comparisons, using the SAS 9.4 program. Results of less than 5% were considered significant.

RESULTS

Out of the 644 ads of devices for sale collected, 636 (98.7%) were automatic, and 8 (1.2%) were semi-automatic; 346 (53.7%) were used in the arm and 298 (46.3%) on the wrist; 625 (97%) were for home usage and 19 (3%) for clinical practice (Figure 1).

The minimum number of devices collected per site was one (sites number 8 and 12, both making up for 0.1% of the sample), and the maximum number of devices collected was 107 (sites number 1 and 5, both making up for 16.6% of the sample). Eleven sites are national and three were international. There was a variation in the average price of the devices, among the sites, from USD 20.10 to USD 87.00 (the values were converted from Brazilian real to US dollar according to the quotation on 03/01/2022, where R$ 1 was equal to USD 0.18) (Table 1). Regarding prices, the home devices varied from USD 10.60 to USD 275.58; among those employed for clinical practice, from USD 106.18 to USD 340.10.

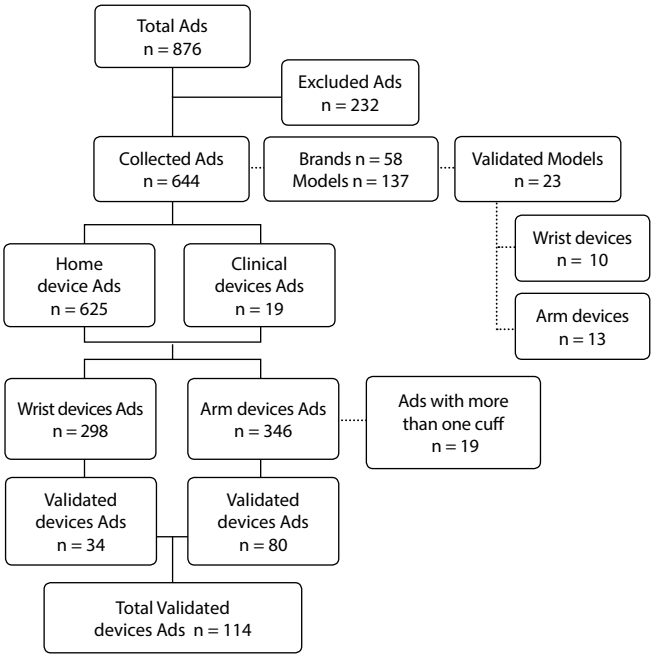

Figure 1 – Flowchart of the number and characterization of ads for oscillometric blood pressure devices, validated and non-validated, available for Brazilian consumers on the Internet

As for clinical validation of devices, only 114 (17.7%) ads contained validated devices. From the 137 devices found, only 23 (16.7%) were validated: 10 wrist devices and 13 arm devices, all validated in the general population. In addition, five were also validated in a special population (three in pregnant women and two in obese people). The European Society of Hypertension International Protocol validated 19 devices in the general population and four special groups (Chart 1).

One device did not pass the approval criteria from the Association for the Advancement of Medical Instrumentation protocol. Besides, 388 (59.3%) ads reported that the device identifies irregular beats or cardiac arrhythmia (CA), but they have not been validated for this diagnosis. None of the devices found were validated to be used in children, older people, and CA situations. Moreover, no device indicated for clinical use was validated.

Table 1 – Characterization of the sites studied according to the frequency of devices considering the price, presented by the mean, standard deviation, and minimum, median, and maximum price (n = 644), Campinas, São Paulo, Brazil, 2020

Web sites		Price (USD)				
	n	Mean	Standard deviation	Minimum	Median	Maximum
1	107	176.16	137.38	58.70	139.90	944
2	72	217.24	239.75	78.58	157.62	1,890
3	87	185.62	97.92	79.90	170	690
4	8	142.91	42.06	78.89	140.97	229.04
5	107	190.97	97.81	89.99	171.83	720.23
6	79	217.87	239.41	79.90	154.25	1,890
7	28	309.11	349.19	96.90	210.15	1,890
8	1	114	-	-	-	-
9	22	319.46	390.79	89.99	193.15	1,890
10	36	483.32	416.24	96	262.87	1,531.54
11	59	278.64	296.54	104.31	175.60	1,776.60
12	1	138	-	-	-	-
13	17	199.02	129.85	95.90	174	665.95
14	20	218.84	123.76	99.80	169.45	666.95

Chart 1 – Characterization of the devices' brand and model approved in the validation study according to the frequency in sales sites, validation in the general and/or special population, the protocol used, and special population studied (n = 114), Campinas, São Paulo, Brazil, 2020

Brand	Model	n	Validated in the general population	Validated in the special population	
			Protocol	Protocol	Population
A&D	UA651	1	*2010	-	-
A&D	UA767F†	1	*2010	-	-
A&D	UA651SL PLUS†	1	‡1993	-	-
BORYUNG	UB525§†	1	*2010	-	-
CITIZEN	CHUD514†	1	*2010	-	-
IHEALTH	Feel BP5	1	*2010	*2010	Pregnant women
IHEALTH	BP7§	1	*2010	-	-
IHEALTH	BP3	1	*2010	-	-
INCOTERM	VISOMAT HANDY§	2	*2002	-	-
MICROLIFE	BPW100§	4	‡1993/*2002	-	-
MICROLIFE	BP3AC1	4	*2002	-	-
MICROLIFE	MAMPC	1	*2002	-	
NISSEI	WSK1011§	1	*2010	-	-
OMRON	HEM7320LA§†	33	*2010	-	-
OMRON	HEM6221E§	23	*2010	-	-
OMRON	HEM7130	30	*2010	-	-
OMRON	HEM6161E§	1	‖2013/*2010	-	-
OMRON	HEM7120E†	1	*2010	-	-
OMRON	HEM7321E†	1	‖2009	¶2018	Pregnant women
OMRON	HEM9210T	1	‖2013	*2010/‖2013	Pregnant women and Obese people
OMRON	HEM7600T	1	*2010	¶2018	Pregnant women
OMRON	HEM6232T§	1	‖2013/*2010	*2010	Obese people
QARDIO	QARDIOARM	2	*2010	-	-

**European Society of Hypertension Protocol; †Founded equivalence; ‡British Hypertension Society Protocol; §Wrist device; ‖American National Standards Institute Protocol/Association for the Advancement of Medical Instrumentation/International Organization for Standardization; ¶European Society of Hypertension Protocol/ Association for the Advancement of Medical Instrumentation/International Organization for Standardization.*

Table 2 – Comparison of device ads according to the place of application, information about the recommendation by scientific society, and approval by validation study, considering the price, presented by mean, standard deviation, minimum, median, maximum, and significance level (*p* value) (n = 644), Campinas, São Paulo, Brazil, 2020

Home devices	n	Price (USD)					*p* value
		Mean	Standard deviation	Minimum	Median	Maximum	
Place of application							
Arm	346	295.02	284.97	88.83	199.45	1,890	**< 0.0001***
Wrist	298	150.63	97.81	58.70	129.90	1,109.53	
Information about recommendation by scientific society							
No	588	218.62	209.33	58.70	160.52	1,890	**< 0.0001***
Yes	56	328.85	377.88	113.90	199	1,890.00	
Information on validation approval							
No information	573	214.42	218.27	58.70	161.21†	1,890.00	
Correct information	26	443.31	369.54	113.90	249.12	1,442.09	**< 0.0001**§
False information	45	279.41	218.52	79.90	181.99‡	929.44	
Validation approval in general/special population							
No	530	204.67	215.85	58.70	152.10	1,890	**< 0.0001***
Yes	114	337.60	264.27	113.90	264.68	1,531.54	

**Value of p obtained using the Mann-Whitney test; †Significant difference in " Correct information" (p < 0,001 – Dunn's post-test); ‡Significant difference for "No information" (p = 0,043 – Dunn's post-test); §Value of p obtained by using the Kruskal-Wallis's test.*

In Table 2, when comparing the price of the arm and wrist home devices, there was a statistically significant difference, so that the arm devices had a median of USD 12.53 more expensive than the wrist ones. In addition, 56 ads for home devices reported being recommended by scientific societies and showed a statistically significant price difference, i.e., they had a median of USD 6.92 more expensive than instruments that did not contain this information. However, only 16 of these ads were for validated devices. The 114 ads that provided the correct validation information had a more expensive median of USD 20.26 than those without this information ($p < 0.001$). The 45 ads that provided false validation information had a median of USD 3.74 more expensive than those without validation information. ($p = 0,043$). There was also a significant difference in price between ads featuring validated versus non-validated devices. The non-validated devices had a cheaper median of USD 20.26.

Only 81 ads (12.5%) informed the cuff size of the device, with variations of S, M, L, M and L, XL, XXL, and others (Table 3). In the others category, we found several nomenclatures, such as adult, average adult, large adult, obese, pediatric, infant, neonatal, making it difficult to categorize according to the variations in size. Twenty-one ads (3.2%) cited the approximate cuffs' width and/or length in centimeters.

Table 3 – Absolute frequency of cuff sizes available in oscillometric devices ads on the Internet (n = 644), Campinas, São Paulo, Brazil, 2020

Cuff Sizes	n	%	C*
S	1	0.2	0.2
M	20	3.1	3.3
L	2	0.3	3.6
M e L	27	4.2	7.8
XL	3	0.5	8.3
XXL	4	0.6	8.9
Other†	26	4	12.9
In centimeters	21	3.3	16.2
Not informed	540	83.8	100

**C – Accumulated Percentage; †Other – Adult, normal adult, large adult, obese people, pediatric, child, and neonatal.*

The 19 ads (3.0%) that informed the presence of more than one cuff size were for arm measurement. Among them, 13 were home devices, with an average price of USD 78.61 higher compared to devices with a single cuff.

Information about the brachial circumference indicated for use in the instruments, with 13 types of bands of different sizes, was found in 246 ads for arm devices (38.1%). For the wrist devices, that information occurred in 80 ads (12.4%) with nine options of wrist circumference bands.

DISCUSSION

This work's main discovery is that most oscillometric devices for sale on the Internet are not validated and are cheaper. Besides, we found ads containing false information on device validation, which were more expensive than those without validation, considering our data collection.

In Brazil, to market PA devices, imported or national instruments must receive the approval of the National Institute of Metrology, Standardization, and Industrial Quality (*Instituto Nacional de Metrologia, Normalização e Qualidade Industrial* -INMETRO), in addition to being registered with the National Health Surveillance Agency to ensure that they meet acceptable quality, safety, and reliability standards. INMETRO requires manufacturers to submit the clinical evaluation results of oscillometric devices using recognized validation protocols[10].

It is incredibly worrisome to exclude 222 ads for not informing the brand and/or model. Without this information, the consumer cannot certify whether the device has undergone any validation study or has been certified by regulatory institutions.

Furthermore, most of the advertisements examined contained claims that the devices were highly accurate, defining that accuracy as submission to testing or calibration. However, they often did not mention whether the device had undergone a validation study, and only 16.7% of the devices were validated. Another study also verified the number of validated oscillometric devices for sale on the Internet in Australia, and only 5.5% were validated[11].

In this study, we ascertained that non-validated devices were cheaper than validated ones, the same finding encountered in the Australian study[11]. Thus, we can assume that cheap BP devices with questionable accuracy are being sold. Consequently, consumers are predisposed to purchase non-validated devices because of the low price.

A study conducted with hypertensive patients identified that 61.3% of participants used non-validated devices at home[12]. Another study observed that 30% of the devices were validated, and 24% were inaccurate[13].

When comparing home oscillometric devices to the auscultatory method, one research identified that the percentage of participants with differences in BP ≥ 5 mmHg was higher in non-validated devices and cuff devices[14]. A study in Turkey showed that among 2,747 hypertensive patients, 46.6% had an oscillometric device, of which 60% were devices with cuff[15]. It is worth mentioning that guidelines and studies have recommended using arm oscillometric devices instead of wrist ones[3,16]. This study identified more arm cuff devices available for sale, but wrist devices were cheaper ($p < 0.0001$), which might have contributed to consumers purchasing these devices.

In addition, the sites employed user reviews to categorize the quality of the devices. These reviews included comments from people who had already purchased the device and rated it according to their experience, something very comprehensive and subjective. However, even though the instrument shows positive reviews, that does not mean it performs a reliable BP measurement. In this context, consumers who are unaware of the validation processes may make the purchase solely based on the information contained on the websites.

A survey conducted with consumers of home oscillometric devices showed that only 1% considered the device's accuracy when purchasing the device. The most common reason for choosing the model was simplicity and practicality (75%)[17]. Another study revealed that only 16% of the devices were purchased by medical recommendation, and 23% were gifts[13].

Apparently, describing the functions of the devices on the collection sites was a marketing strategy. Only 71 ads contained validation information. Out of these, 45 presented false information, which is a violation of the Brazilian Consumer Defense Code (*Código de Defesa do Consumidor*)[18] and the e-commerce

law[19]. Unfortunately, manufacturers' false claims regarding BP measurement are not recent but systematic[7].

In this study, only five devices were validated in special populations (three in pregnant women and two in obese people), and no devices for clinical use were validated. Considering that the oscillometric waveform does not have the same pattern in all population groups, it may be affected by age, degree of arterial compliance, and pulse pressure[2]. Thus, even if a device has been validated in the general population, validation should be encouraged in obese people, children, pregnant women, and people with atrial fibrillation[20-21].

Conducting and publishing new validation studies worldwide using the Universal Standard protocol (ISO 81060-2:2018) is essential for the reliability of the devices to be tested in the general population and special groups[3]. The shortage of devices for sale validated for special populations is worrisome because these groups may be using inaccurate devices. In pregnancy, the usage of validated oscillometric devices is indispensable due to the gestational-specific hemodynamic changes and possible complications, such as gestational hypertensive syndromes (GHS). There are even recommendations that pregnant women with GHS perform HBPM to manage hypertension, considering preeclampsia's rapid and unpredictable evolution[21-22].

In children, the BP measurement presents several difficulties involving anatomical and physiological aspects. Although Korotkoff sounds are difficult to auscultate in children, current guidelines recommend using office auscultation for the diagnosis of SAH. So far, evidence on the accuracy of BP oscillometric monitors in children is limited, and further validation studies in this population are required[20].

Another fact that draws attention in this study is the advertisement informing that some instrument identifies CA, but there was no validated device for this diagnosis. During data collection, we discovered a device containing a specific algorithm for atrial fibrillation detection during BP measurement, demonstrating good diagnostic accuracy[23], but it did not undergo a validation protocol.

One of the most significant limitations of the oscillometric method is its use in patients with CA, since when there is a change in amplitude, configuration, and frequency of blood oscillations[2], the oscillometric method is not able to detect this variation, and may generate inaccurate BP results, thus the need for independent validation in people with CA[20].

The BP measurement in obese people is associated with increased arm circumference (AC), which requires more oversized BP cuffs[3]. The Universal Standard protocol (ISO 81060-2:2018) considers validation in obese subjects with an AC ≥ 42 cm[20]. In addition, different cuff sizes also need to be tested regarding validation[3].

In this study, only 16.2% of the ads informed the size of the cuff that went along with the device. From the ads analyzed, 50.5% reported the range of AC/wrist indicated for the device; all were wide-range cuffs. Wide-range cuffs have a standard cuff size but are marketed for use in an AC range and currently dominate the oscillometric device market[24]. Another study pointed out that despite an oscillometric device recommending the 13 centimeter cuff for AC from 22 cm to 42 cm, it occurred an underestimation of BP in pregnant women, with the indication of smaller cuffs[22].

Some manufacturers claim to use cuffs that adapt to each person's AC, giving an individualized measurement. Theoretically, the oscillometric measurement can be adjusted to the arm's size through a parameter incorporated into the algorithm, such as inflation time and/or volume of air needed for inflation, using regression equations or similar methods. However, since the algorithms are not publicly disclosed, it is unclear how the manufacturers perform this adjustment[22].

Recently the Universal Standard protocol (ISO 81060-2:2018) has incorporated more rigorous requirements for the AC range to minimize measurement errors related to participants with AC who fall within the extreme cuffs ranges[20]. However, further studies need to be conducted to evaluate the performance of the wide-range cuffs. In addition, the companies involved in manufacturing the devices should consider the interference of the cuff size in the oscillometric measurement, inform the cuffs width and length, and make available on the Internet the purchase of different cuff sizes.

Study limitations

Because of the focus of this study, the data collected was extracted exclusively from the electronic marketplace, which may have underestimated the number of device models available for sale.

Contributions to the Fields of Nursing, Health or Public Policy

The release of the list of validated devices presented in this paper is of great value, as it aims to promote the usage of validated devices for consumers in general, nursing professionals, and other categories.

Due to numerous unproven BP devices available for sale on the Internet, the study points out the need to make it mandatory for devices to pass validation studies prior to release for sale. The role of regulatory agencies is indispensable in this context. However, the standards need to be reviewed and applied thoroughly in evaluating devices to prevent inaccurate devices containing fraudulent information from reaching the market and jeopardizing the safety of patients and consumers in general. The formulation of new legislation in this area and the inspection of the electronic market by the responsible bodies are essential to identify sales of counterfeit products and abusive practices.

In order to contribute to changing this scenario, it is essential to carry out health education actions on the subject, in addition to disseminating specific regulations that guide manufacturers, websites, online stores, retailers, consumers, institutions, and health professionals about the regulatory processes and good practices involving the validation and marketing of BP measurement devices.

CONCLUSIONS

There were only 23 devices for sale approved in validation studies, i.e., the smallest part of the identified devices was validated, a procedure that mainly involved the general population. When validation took place, several protocols were used. The validated devices were more expensive than non-validated devices. There were identified advertisements with false information about the submission to validation protocols, and these ads were for more expensive devices than those that did not provide validation information.

SUPPLEMENTARY MATERIAL

References to BP oscillometric devices approved by validation studies are available at https://data.scielo.org/dataset.xhtml?persistentId=doi:10.48331/scielodata.5S5BPM.

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