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Original Article

Validity of Home Blood Pressure Devices Sold in Canada

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ABSTRACT

Background: Measurement of home blood pressure is an important tool for the management of hypertension. However, the validity of home devices is of concern. The Recommended Blood Pressure Devices Program of Hypertension Canada reviews and recommends blood pressure devices using international validation standards. We sought to determine the proportion of Hypertension Canada-recommended devices available for purchase in pharmacies and online.

Methods: We visited 16 community pharmacies in the Edmonton area to record the blood pressure devices they sold. We also reviewed the 50 most popular devices from online retailers (Amazon, Walmart, Best Buy, and Canadian Tire). All devices were referenced against the Recommended Blood Pressure Device Program of Hypertension Canada (www.hypertension.ca/bpdevices) to determine if the models were recommended.

Results: We reviewed 170 devices. Of those sold in pharmacies, 61 of 68 (89.7%) were Hypertension Canada-recommended devices,

RÉSUMÉ

Contexte : La mesure de la pression artérielle au domicile est un outil important dans la prise en charge de l'hypertension. Or, il semble que les appareils utilisés à la maison à cette fin ne soient pas toujours des dispositifs validés. Dans le cadre de son Programme de recommandation d'appareils de mesure de la pression artérielle, Hypertension Canada analyse et recommande des tensiomètres selon des normes de validation internationales. Nous avons donc cherché à déterminer la proportion des tensiomètres recommandés par Hypertension Canada qu'il est possible d'acheter dans les pharmacies et en ligne.

Méthodologie : Nous avons rendu visite à 16 pharmacies communautaires dans la région d'Edmonton pour recenser les tensiomètres qui y étaient vendus. Nous avons également analysé les 50 tensiomètres les plus vendus par des détaillants en ligne (Amazon, Walmart, Best Buy et Canadian Tire). Nous avons vérifié si chacun des modèles faisait partie de la liste des appareils recommandés par Hypertension Canada (www.hypertension.ca/bpdevices).

More than 1.4 billion people worldwide have hypertension, leading to 10.8 million annual deaths, predominantly from cardiovascular causes.[1] The World Health Organization estimates that only 21% of individuals with hypertension have their blood pressure controlled.[2] Accurate and precise measurement of blood pressure is a fundamental principle for the diagnosis and management of hypertension. Errors of even only 5 mm Hg can lead to misclassification of individuals, leading to over- and undertreatment of hypertension.[3-5]

It is not widely known that there is no regulatory requirement for blood pressure devices to be tested for accuracy and precision (often referred to as validation studies). Recent studies and a consensus statement of the World Hypertension League and leading hypertension professional organizations have raised the concern over the high proportions (up to 94.5%) of unvalidated devices on the market.[5-7]

In Canada, the Recommended Blood Pressure Devices Program of Hypertension Canada provides a publicly available listing of recommended automated oscillometric blood pressure devices (www.hypertension.ca/bpdevices). To be considered for listing, device manufacturers submit their peer-reviewed validation studies to the program, and they are adjudicated by at least 2 expert reviewers. The program reviews the studies according to internationally recognized standards: the ISO Standard 2018, AAMI 2013, and BHS 1993 (for "Gold" designation) and the ESH Revised Protocol 2010 (for "Silver" designation). The rationale and processes for the program have been published in detail previously.[8]

In the face of declining rates of control of hypertension in Canada,[9] we need new tools and tactics. Although home blood

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whereas online retailers had only 46 of 102 (45.1%) recommended devices; $P < 0.001$.

Conclusions: Most blood pressure devices sold in pharmacies are Hypertension Canada recommended, in contrast to less than one-half from online retailers. The lack of validation of many home blood pressure devices could have important clinical implications, leading to over- or undertreatment of hypertension. Clinicians should advise patients on the importance of home blood pressure device validation and direct them to resources such as Hypertension Canada (https://hypertension.ca/public/recommended-devices) for guidance.

Résultats : Nous avons passé en revue 170 appareils. Dans les pharmacies, 61 appareils sur 68 (89,7 %) étaient recommandés par Hypertension Canada, alors qu'en ligne, cette proportion n'était que de 46 sur 102 (45,1 %); $p < 0{,}001$.

Conclusions : La plupart des tensiomètres vendus dans les pharmacies sont recommandés par Hypertension Canada, contrairement à moins de la moitié de ceux qui sont vendus en ligne. L'absence de validation pour de nombreux tensiomètres pourrait avoir d'importantes conséquences cliniques, menant à un traitement excessif ou insuffisant de l'hypertension. Les cliniciens doivent informer les patients de l'importance d'utiliser un tensiomètre validé à la maison et les orienter vers des ressources comme Hypertension Canada (https://hypertension.ca/public/recommended-devices) pour guider leur choix.

pressure monitoring is an important tool for patient engagement and better control of blood pressure,[10] the concerns over accuracy and precision are equally applicable for these devices. Many Canadians purchase blood pressure devices at pharmacies or—increasingly—from online retailers. Given the importance of accurate measurement of blood pressure, we sought to determine the proportion of Hypertension Canada-recommended devices available for purchase at pharmacies and online.

Methods

We conducted a cross-sectional study during July 2022. We selected a convenience sample of chain and independent pharmacies in the Edmonton area. We then secretly visited these 16 pharmacies, representing 7 major chains and 9 independent pharmacies. If a selected pharmacy also had an online store, we included those blood pressure devices as being available in the pharmacy. We recorded the upper-arm home blood pressure devices sold at each pharmacy.

We selected the top online retailers by performing a Google search of the term "blood pressure monitor" and took the first 3 that also had brick and mortar stores (which were Walmart, Best Buy, and Canadian Tire in July 2022). We also selected the ubiquitous Amazon.ca as an online retailer. For Amazon, we reviewed the 50 most popular devices; for others, we chose only those devices sold directly by the retailer.

For all home blood pressure devices, we checked the model against the Hypertension Canada website (hypertension.ca/bpdevices) to determine if they were Hypertension Canada-recommended devices.

We conducted several post hoc analyses, including the proportion of recommended devices sold at pharmacies vs online retailers using the χ^2 test and Clopper Pearson exact method to calculate the 95% confidence interval (CI). We also descriptively reported differences between independently owned and chain pharmacies in terms of sales of recommended devices. Finally, we collected and reported the median differences in cost between recommended and not recommended devices using the Mann-Whitney U test, as the costs were not normally distributed.

Results

We reviewed a total of 170 devices (113 unique devices), of which 107 (62.9%) were Hypertension Canada-recommended devices (Table 1). Of those sold in pharmacies, 61 of 68 (89.7%; 95% CI, 79.93%-95.76%) were Hypertension Canada-recommended, whereas only 46 of 102 (45.1%; 95% CI, 35.22%-55.26%) from online retailers were recommended; $P < 0.001$(Table 1). Independent pharmacies had the highest percentage of Hypertension Canada-recommended devices (100%) compared with 85.1% in chain pharmacies.

Median device cost was $84.98 (interquartile range [IQR]: $57.77-$109.99). Validated devices were generally more expensive than nonvalidated devices: median of $96.99 (IQR: $74.99-$119.99) vs $50.12 ($40.99-$69.99), respectively ($P < 0.00001$).

Discussion

Home blood pressure devices are an important tool for the management of hypertension; however, there are significant concerns about their accuracy and precision.[3-7] We found that most home blood pressure devices sold in pharmacies are Hypertension Canada-recommended (ie, have met international standards for accuracy and precision). However, less than one-half of devices available from online retailers meet these standards; this could have important clinical implications.

Compared with previous international investigations, Canada appears to have a relatively high availability of validated home blood pressure devices (perhaps because of the Hypertension Canada-Recommended Blood Pressure Device Program. Recently, Picone and colleagues reviewed validation status of 3411 devices listed on the Medaval database and found that there was no evidence of validation for 76.3% of devices.[6] Similarly, a search of 59 online retailers in Australia showed very high proportions (81.7% to 94.5%) of unvalidated devices.[7] Indeed, this has led to a statement on the urgency to regulate validation of blood pressure devices from the World Hypertension League and affiliates.[5] Validated blood pressure devices are shown to provide more accurate blood pressure readings. Accurate readings provide reliable diagnoses and treatment, whereas inaccurate readings can result in incorrect diagnoses and inappropriate treatment.[3-5]

Not surprisingly, we found that unvalidated devices are typically cheaper than validated devices. This would have implications for health equity, as blood pressure devices are not covered by provincial health plans, and patients with lower income levels might then turn to cheaper unvalidated devices found online.

Limitations

Limitations of this study include our limited sampling of pharmacies from the Edmonton area only. However, chain

Table 1. Proportion of Hypertension Canada recommended blood pressure devices sold in Canada

	Proportion of Hypertension Canada- recommended home blood pressure devices
Overall	62.9% (107 of 170)
Pharmacy overall	89.7% (61 of 68)
Online overall	45.1% (46 of 102)
Independent pharmacies	100% (21 of 21)
Chain pharmacies	85.1% (40 of 47)
Amazon	30.0% (15 of 50)
Walmart	57.1% (16 of 28)
Best Buy	65.0% (13 of 20)
Canadian Tire	50.0% (2 of 4)

pharmacies use the same wholesalers across the country, so our results are likely generalizable. Similarly, even independent pharmacies have only few choices of wholesale suppliers. Nevertheless, it was not a truly random sample of pharmacies, which was not feasible. In addition, our selection of online retailers was also not random; appearing earlier in a Google search does not guarantee that the retailer is truly a "leading" retailer (although this might be how the public might select them).

The comparison of recommended devices sold in pharmacies vs online was not a prespecified hypothesis; however, upon conducting a post hoc power analysis, the power to see the difference we observed was 100%, so it is unlikely because of chance.

Finally, we only used the Hypertension Canada-recommended list. We acknowledge that there are other organizations that list validated blood pressure devices that have slightly different methods. Dabl (http://www.dableducational.org/) provides a list of validated blood pressure devices from experts who review blood pressure device validation studies. Manufacturers have the option of requesting devices to be recognized as equivalent to existing Dabl-validated devices. The STRIDE BP (https://www.stridebp.org) validated device list is developed from monthly reviews of peer-reviewed validation studies listed on PubMed or manufacturers providing data on devices shown to be equivalent or identical to existing STRIDE BP-validated devices. The Medaval (https://www.medaval.ie) validated blood pressure list is created from reviewing monthly searches of blood pressure device studies listed on PubMed. Manufacturers can request for devices to be validated by Medaval. As such, the methods of the Hypertension Canada program might miss some valid devices that have not been submitted for review.

The implications of inaccurate blood pressure devices are incorrect diagnoses and, potentially, over-, or undertreatment. And there are other factors that affect the quality of the blood pressure measurements such as requires correct cuff size, patient preparation (rest for at least 5 minutes), and correct positioning (https://hypertension.ca/how-do-i-monitor-my-bp/), all of which would compound the problem of inaccurate home devices. For a condition that affects 23% of adult Canadians, this has real public health implications.

Conclusions

Many home blood pressure devices sold in Canada are not validated for accuracy and precision. Although we found that almost all devices sold in pharmacies in Canada are validated and Hypertension Canada recommended, the proportion of validated devices available through online retailers is concerningly low. Clinicians should advise their patients on the importance of validation of home blood pressure devices and recommend that patients avoid online retailers for such devices. A useful resource for patients is available on the Hypertension Canada website: https://hypertension.ca/public/recommended-devices.

Ethics Statement

This paper was exempt from research ethics review.

Patient Consent

No patients were involved in this study; therefore, consent was not necessary.

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Disclosures

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