Accuracy of Blood Pressure Measurement Devices in Pregnancy

A Systematic Review of Validation Studies

Natalie A. Bello, Jonathan J. Woolley, Kirsten Lawrence Cleary, Louise Falzon, Bruce S. Alpert,* Suzanne Oparil, Gary Cutter, Ronald Wapner, Paul Muntner, Alan T. Tita, Daichi Shimbo

***Abstract*—**The accurate measurement of blood pressure (BP) in pregnancy is essential to guide medical decision making that affects both mother and fetus. The aim of this systematic review was to determine the accuracy of ambulatory, home, and clinic BP measurement devices in pregnant women. We searched Ovid MEDLINE, The Cochrane Library, EMBASE, CINAHL EBSCO, ClinicalTrials.gov, International Clinical Trials Registry Platform, and dabl from inception through August 3, 2017 for articles that assessed the validity of an upper arm BP measurement device against a mercury sphygmomanometer in pregnant women. Two independent investigators determined eligibility, extracted data, and adjudicated protocol violations. From 1798 potential articles identified, 41, that assessed 28 devices, met the inclusion criteria. Most articles (n=32) followed a standard or modified American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization, British Hypertension Society, or European Society of Hypertension validation protocol. Several articles described the results of validation studies performed on >1 device (n=7) or in >1 population of pregnant women (n=12), comprising 64 pairwise validity assessments. The device was validated in 61% (32 of 52) of studies which used a standard or modified protocol. Only 34% (11 of 32) of the studies wherein the device was successfully validated were performed without a protocol violation. Given the implications of inaccurate BP measurement in pregnant women, healthcare providers should be aware of and try to use the BP measurement devices which have been properly validated in this population. **(*Hypertension*. 2018;71:326-335. DOI: 10.1161/HYPERTENSIONAHA.117.10295.)** • **Online Data Supplement**

Key Words: blood pressure ■ blood pressure monitors ■ hypertension ■ preeclampsia ■ pregnancy ■ sphygmomanometers

Hypertension is one of the most common medical disorders complicating pregnancy, occurring in up to 10% of pregnancies.[1] Hypertensive disorders of pregnancy include chronic hypertension, gestational hypertension, preeclampsia, and preeclampsia superimposed on chronic hypertension.[1] Complications associated with hypertension in pregnancy include placental abruption, preterm delivery, fetal growth restriction, stillbirth, maternal death secondary to stroke and eclampsia, as well as future risk of hypertension, diabetes mellitus, and cardiovascular disease.[1–6] Blood pressure (BP) control is recommended to help prevent maternal-fetal adverse outcomes.[1,7] However, the optimal BP goal for pregnant women with hypertension is uncertain.[8] Prior and ongoing randomized trials are investigating the effect of more intensive BP control in pregnant women with hypertension.[7,9] Because hemodynamic and vascular changes occur during pregnancy, guidelines recommend validating BP measurement devices in pregnant women.[10,11]

The Association for the Advancement of Medical Instrumentation (ANSI/AAMI/ISO), British Hypertension Society (BHS), and European Society of Hypertension (ESH) have published protocols to validate BP measurement devices and ensure that their accuracy is comparable to the reference standard, a mercury sphygmomanometer.[10–16] These protocols were developed to standardize the procedures for validating BP devices,[17,18] and strict adherence to an individual protocol is necessary for accuracy and statistical validity.[19]

Given the importance of measuring BP accurately in pregnancy, we undertook a systematic review of published studies assessing the validity of ambulatory, home, and clinic BP measurement devices in pregnant women to evaluate the methodology and quality of the published validation data.

Received September 11, 2017; first decision October 3, 2017; revision accepted November 16, 2017.

From the Department of Medicine (N.A.B., L.F., D.S.) and Department of Obstetrics and Gynecology (K.L.C., R.W.), Columbia University Medical Center, New York, NY; Department of Economics, California Polytechnic State University, San Luis Obispo (J.J.W.); Department of Pediatrics, University of Tennessee Health Science Center, Memphis (B.S.A.); and Department of Medicine (S.O.), Department of Biostatistics (G.C.), Department of Epidemiology (P.M.), and Department of Obstetrics and Gynecology and Center for Women's Reproductive Health (A.T.T.), University of Alabama at Birmingham.

*Retired.

The online-only Data Supplement is available with this article at http://hyper.ahajournals.org/lookup/suppl/doi:10.1161/HYPERTENSIONAHA.117.10295/-/DC1.

Correspondence to Natalie A. Bello, Division of Cardiology, Columbia University Medical Center, 622 W 168th St, PH 3-342, New York, NY 10032. E-mail nb338@columbia.edu

Methods

The authors declare that all supporting data are available within the article (and its online supplementary files). We followed the guidelines from the Cochrane Handbook for Systematic Reviews[20] and the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines.[21] All methods and inclusion/exclusion criteria were specified in advance and documented in a study protocol as described below.

Inclusion and Exclusion Criteria

Articles that assessed the validity of an upper arm brachial BP measurement device compared with a traditional mercury sphygmomanometer in pregnant women were included. Articles were excluded if they examined devices that measured BP from an anatomic site other than the upper arm, if they used intra-arterial comparisons, random-zero sphygmomanometers, or other devices as the reference standard. If studies included both pregnant and nonpregnant women, they were excluded if they did not report results for pregnant participants separately from nonpregnant participants. Commentaries, meeting abstracts, editorials, book chapters, and review articles were also excluded. There was no restriction on language.

Literature Search Strategy

The following databases were searched from inception through August 3, 2017: Ovid MEDLINE, The Cochrane Library, EMBASE, CINAHL EBSCO, ClinicalTrials.gov, and International Clinical Trials Registry Platform. The search strategies are provided in the online supplemental material (Methods in the online-only Data Supplement). To supplement the database searches, a PubMED similar articles search and a cited reference search through the ISI Web of Science were conducted using articles identified from the first set of results. The dabl Educational Trust Website (http://www.dableducational.org/) was searched manually. A manual search was also performed using the reference lists from the included articles, and from review articles produced by the Ovid MEDLINE search.

Study Selection

Article eligibility was determined by 2 investigators (N.A. Bello and J.J. Woolley) who independently reviewed the title and abstract of all identified articles. If an article appeared to meet the inclusion criteria on reviewing the abstract, the full-text version of the article was retrieved for review. In the event, the 2 investigators (N.A. Bello and J.J. Woolley) disagreed on an article's eligibility, a third investigator (D. Shimbo) resolved the discrepancy.

Data Extraction

Two reviewers (N.A. Bello and J.J. Woolley) independently abstracted all data using standardized data abstraction forms. The data extraction results were compared and discrepancies were resolved by a third investigator (D. Shimbo). Information was extracted on sample size, trimester of pregnancy, systolic and diastolic BP (SBP and DBP) at study entry, and arm circumference, as well as the validation protocol(s) used and specific procedures followed during the protocol, including details on (1) the BP device being evaluated; (2) the arm used for measurement by the device and reference; (3) the sequence of device and reference measurements; (4) the number of BP comparisons between the device and reference obtained; (5) the timing of observer comparisons (sequential versus simultaneous); and (6) final SBP and DBP validation grades for the device. The device type (ambulatory, home, clinic, and home/clinic) was based on the authors' reported description. If the authors did not specify the device type, it was categorized based on other authors' classification or the device manufacturer's specification. If an article reported the validation of >1 device, or 1 device in >1 population of pregnant women (eg, those with and without preeclampsia), the results are reported separately for each device and population. For the purposes of this systematic review, a population is defined as a unique group of pregnant women described in an article which had data on BP and validation grade. A study is defined as the testing of a BP device within a population.

Definition of SBP and DBP

SBP by auscultation is defined by convention as the first appearance of clear, repetitive sounds for at least 2 consecutive beats (K1). There has been controversy and a lack of consensus on whether K4 or K5 should be used to define DBP in pregnancy.[22] Consistent with the National High Blood Pressure Education Program Working Group Report on High Blood Pressure in Pregnancy, we chose to use K5, the point at which all Korotkoff sounds disappear, to define DBP in the current study.[23] Several articles report both K4 and K5 as DBP. In this situation, DBP is presented as K5. There were 2 studies in which only K4 was reported as DBP.[24,25]

Assessment of Methodological Quality and Protocol Violations

Adherence was assessed for each study published in articles that used protocols proposed by the AAMI (1987), BHS (original 1990 or revised 1993 version), and the ESH-international protocol (IP; original 2002 version or revised 2010 version) to perform the validation study. In addition to extracting the authors' reported SBP and DBP grade for the devices, we independently determined the SBP and DBP grades for each device using data in the published articles. Similar to the classification system used to examine BP devices in other reviews, protocol violations were adjudicated and classified as major or minor, as defined in Table S1 in the online-only Data Supplement.[18,26,27] In some articles, the authors report additional grades based on a second validation protocol. In this situation, we extracted the reported SBP and DBP grade for each device and independently adjudicated grades. For articles that used a nonstandard protocol to perform the validation study including 2 for which only K4 was reported for DBP,[24,25] no grades or violations are reported.

Results

A total of 2758 articles were identified and screened for inclusion (Figure). Of these, 960 duplicates were excluded leaving 1798 unique articles. Another 1686 articles were excluded based on abstract review, and the remaining 112 articles were assessed for eligibility based on full-text review. Of the 112 articles, 41 met the inclusion criteria for the current analysis.[24,25,28–66] The 41 articles included >2000 pregnant women with sample sizes ranging from 10 to 170 (Table S2). The majority of articles (n=18) included women in the latter 2 trimesters of pregnancy, and 10 articles included women in all trimesters. Table S3 displays the devices, sample population, reference mean BP, and mean device-reference BP difference for each article. Twelve articles[25,32–36,39,42,44,50,62,63] described the results of device validation in >1 population of pregnant women (eg, normotensive women, hypertensive women, and women with preeclampsia).

Overall, the 41 included articles examined 28 different devices; 5 were designated by the authors as ambulatory devices (Table 1), 5 as home devices (Table 2), and 14 as clinic devices (Table 3). Four devices (Omron T9P,[31] Omron MIT Elite,[33] Microlife 3BTO-A, and Omron M7[57]) were designated as appropriate for use in both the clinic and home settings by the authors; these studies are listed in both Tables 2 and 3. The Spacelabs 90207 ambulatory BP monitor was tested most often (n=10 articles).[30,39,41,47,53,54,59,64–66] The majority of devices (n=23) examined used the oscillometric method, and the remainder of devices (n=5) used the auscultatory method. Of the 41 included articles, 31 used a standard validation protocol or a modification of one (Tables 1 through 3): 1 used the AAMI protocol, 27 used the BHS (7 used the 1990 version and 2 used a modification of it, and 18 used the 1993 version),

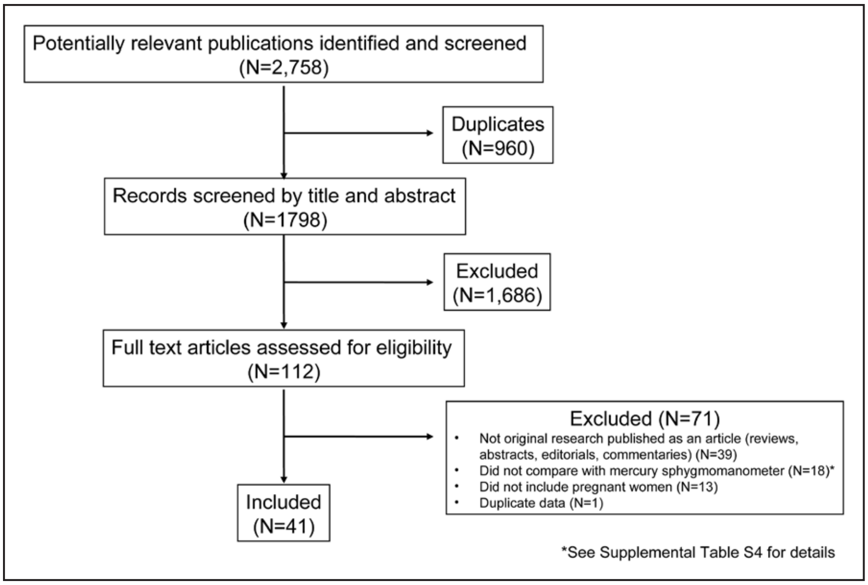

Figure. Process of study selection.

3 used the ESH-IP (2 used the 2002 version and 1 used the 2010 version). With one exception,[46] the authors' published grades for the devices matched our adjudicated grades.

Ambulatory Devices

The devices passed validation in 6 of the 16 studies in which ambulatory BP monitoring devices were examined using a standard protocol (Table 1). Among the 16 studies, 2 had no protocol violations,[28,60] 4 had at least 1 minor violation,[38,54,64] 3 had at least 1 major violation,[39] and 7 had major and minor violations.[40,41,47,59,65,66] Of the 5 ambulatory devices, 3 (BP Lab, Spacelabs 90207, and Welch Allyn QuietTrak) passed at least 1 standard validation protocol. The Disetronic Profilomat[41] and Oxford Medilog[40] each failed 1 standard validation protocol. The BP Lab passed validation in 2 of 2 studies[28,38]; 1 of the 2 studies had no protocol violations.[28] The Spacelabs 90207 passed in 3 of 10 studies; all 3 studies had at least 1 major or minor protocol violation.[39,64] The Welch Allyn QuietTrak passed in 1 of 2 studies without a protocol violation.[54,60]

Home Devices

Of the 18 studies in which home BP measurement devices were examined using a standard protocol (Table 2), the devices passed validation in 13 studies, 3 of which had no protocol violations,[32,33,35] 7 had at least 1 minor violation,[32,33,35,44,63] 1 had at least 1 major violation,[35] and 2 had major and minor violations.[31,35] The Microlife WatchBP Home and the Omron MIT, and T9P passed in all studies; 2 of these 5 (40%) studies had no violations.[31,32,35]

Clinic Devices

Of the 24 studies in which clinic BP measurement devices were examined using a standard protocol (Table 3), the devices passed the validation in 17 studies, 7 of which had no protocol violations,[33,34,36,37] 7 had at least 1 minor violation,[33,42,48,55–57,62] 1 had at least 1 major violation,[36] and 2 had major and minor violations.[31,42]

Overall, among pregnant women, 61% of devices passed the stated validation protocol in at least 1 study, and 34% of those devices passed without a protocol violation (Table 4).

Discussion

In this systematic review, we found that the majority of BP measurement devices passed a validation protocol in pregnant women, but that only one-third of these devices did so without any protocol violations. The most common major protocol violation was the inclusion of too few pregnant women when a population was examined, so that too few comparisons were obtained between the device and the reference standard. The most common minor violations were related to arm circumference and SBP and DBP ranges. Of the 11 categories of protocol violations, only 2 did not occur: the use of the same/opposite arm (major) for device and reference standard, and inclusion of at least 10 women in each of the second and third trimesters of pregnancy (minor). Although not considered a violation, in 1 article[31] the authors followed a modified BHS 1990 protocol,[16] but evaluated the results using grading criteria from the BHS 1993 protocol.[10,15] The BHS 1993 protocol is more lenient than the 1990 BHS protocol, requiring fewer participants, examining a narrower range of BP, and requiring less stringent grading criteria to pass validation. Additionally, all studies which undertook the 1993 BHS protocol[10] reported a letter grade for SBP and DBP despite the recommendation that grading should not be attempted in special groups such as pregnant women.

Substantial hemodynamic changes occur during pregnancy, including increased blood volume, stroke volume, heart rate, and consequently cardiac output along with a decrease in peripheral vascular resistance[67,68] Thus, guidelines recommend BP devices intended for use in pregnant women should be validated in this population.[10,11] Accurate measurement of BP enables the timely diagnosis, monitoring, and treatment of hypertensive disorders of pregnancy.[68] However, it is important to note that although validation protocols provide reassurance that a device has been validated for use in a population, the device is not necessarily accurate in all individuals. When possible, devices should be tested against a traditional sphygmomanometer in individual patients to confirm accuracy before clinical use.[69]

Table 1. Validation Studies of Ambulatory Devices

				BHS Grade (SBP/DBP)		ESH Grade (SBP/DBP)		AAMI Grade (SBP/DBP)		Violations	
Device	First Author (Year)	Protocol(s)	Population (n)	Pub	Adj	Pub	Adj	Pub	Adj	Major	Minor
BP Lab	Bartosh (2006)	ESH 02	Normotensive (without preeclampsia) and hypertensive (with and without preeclampsia; n=33)*†	…	…	P/P	P/P	…	…	None	None
	Dorogova (2015)	BHS 93	Normotensive and hypertensive (n=30)*†	A/A	A/A	…	…	…	…	None	Circ
Disetronic Profilomat	Franx (1997)	BHS 90‡ Additional: AAMI	Pregnancy (n=55)*	B/C	B/C	…	…	P/P	P/P	n,‡ comp‡	SBP, DBP
Oxford Medilog	Franx (1994)	BHS 90 Additional: AAMI	Pregnancy (n=30)*	C/C	NG	…	…	P/P	P/P	n, comp	SBP, DBP
Spacelabs 90207	Brown (1998)	Nonstandard	Normotensive and hypertensive (n=79)*	…	…	…	…	…	…	…	…
	Elvan-Taspinar (2003)	BHS 93 Additional: AAMI	Normotensive, hypertensive, and preeclampsia (n=123)	B/B	B/B	…	…	P/P	P/P	Obs	None
			Normotensive (n=54)*†	A/A	A/A	…	…	P/P	P/P	Obs	None
			Preeclampsia (n=31)*	B/C	B/C	…	…	F/F	F/F	Obs	None
			Hypertensive (n=38)*†	B/A	B/A	…	…	P/P	P/P	Obs	None
	Franx (1997)	BHS 90‡ Additional: AAMI	Pregnancy (n=55)*	B/C	B/C	…	…	P/P	P/P	n‡, comp‡	SBP, DBP
	Koenen (1998)	BHS 90	Pregnancy (n=10)*	NR	NG	…	…	…	…	n, comp	SBP, DBP
	Montan (1995)	Nonstandard	Preeclampsia (n=20)*	…	…	…	…	…	…	…	…
	Natarajan (1999)	BHS 93 Additional: AAMI	Preeclampsia (n=30)*	D/D	D/D	…	…	F/F	F/F	None	Circ, SBP, DBP
	Obrien (1993)	BHS 90 Additional: AAMI	Pregnancy (n=86 recruited, n=81 included in the analysis)*	A/C	A/C	…	…	P/F	P/F	n, comp	SBP, DBP
	Shennan (1993)	BHS 90 Additional: AAMI	Pregnancy (n=122)*†	B/B	B/B	…	…	P/P	P/P	None	n, comp, SBP, DBP
	Shennan (1996)	BHS 90	Preeclampsia (n=30)*	C/C	NG	…	…	…	…	n, comp	SBP, DBP
	Tape (1994)	AAMI	Pregnancy (n=59)*	…	…	…	…	P/P	NG	n	SBP, DBP
Welch Allyn QuietTrak	Natarajan (1999)	BHS 93 Additional: AAMI	Preeclampsia (n=30)*	D/D	D/D	…	…	F/F	F/F	None	Circ, SBP, DBP
	Penny (1996)	BHS 93 Additional: AAMI	Pregnancy (n=85)*†	B/B	B/B	…	…	F/F	F/F	None	None

When >1 protocol is listed, the first protocol is the methodology followed for the validation study and additional protocols are listed when their grading criteria were applied to the data. A indicates age; Adj, adjudicated grade; BP, blood pressure; Circ, arm circumference; comp, number of BP comparisons; DBP, diastolic blood pressure range; G, final grade; n, number of participants; NG, not able to adjudicate a grade; NR, not reported; Obs, observer measurements simultaneous/sequential; Pub, published grade; SBP, systolic blood pressure range; T, trimester; and timing, device vs mercury simultaneous/sequential.

*Individual studies in the population column.

†Studies that passed the primary protocol.

‡Protocol Modification: Authors state they used BHS 90 criteria to enable comparison with prior studies of Spacelabs device but fewer participants because the BHS 93 allows for ≥30.

Obstetric guidelines[1] suggest frequent monitoring of BP in the clinic and at home for pregnant women with poorly controlled BP and those at high risk of developing preeclampsia. Preeclampsia, the concurrent development of elevated BP after 20 weeks of gestation accompanied by proteinuria or organ dysfunction, is a significant contributor to maternal-fetal morbidity and mortality.[23] In light of the evidence that the treatment of preeclampsia can reduce maternal-fetal morbidity and mortality, the US Preventive Services Task Force recently updated its preeclampsia screening guideline to recommend BP measurements be obtained during each prenatal care visit (grade B).[70,71] Several devices have undergone validation studies (n=17) among pregnant women with preeclampsia. These included 4 studies of ambulatory BP monitors,[39,54,65] 8 studies of home BP devices,[32,33,35,44,57,63] and 5 studies of clinic BP devices.[33,36,42,57,62] Of these studies, no ambulatory device passed validation; 5 of the home devices (Microlife 3BTO-A,[63] Microlife WatchBP Home,[32] Omron M7 and MIT,[35] and Omron MIT Elite[33]), and 3 clinic devices (Dinamap ProCare 400,[36] Omron MIT,[42] and Omron MIT Elite[33]), the latter 2 of

Table 2. Validation Studies of Home Devices

Device	First Author (Year)	Protocol(s)	Population (n)	BHS Grade (SBP/DBP)		ESH Grade (SBP/DBP)		AAMI Grade (SBP/DBP)		Violations	
				Pub	Adj	Pub	Adj	Pub	Adj	Major	Minor
Microlife 3BTO-A	Nouwen (2012)*	ESH 02 Additional: BHS 93†	Hypertensive preeclampsia (n=33)‡	B/B	B/B (BHS 93) C/C (BHS 90)	F/F	F/F	…	…	None	A, SBP, DBP
	Reinders (2005)	BHS 93 Additional: AAMI	Pregnancy (n=105)	A/B	A/B	…	…	P/P	P/P	None	Circ
			Normotensive (n=35)‡§	A/B	A/B	…	…	P/P	P/P	None	Circ
			Hypertensive (n=35)‡§	B/B	B/B	…	…	P/P	P/P	None	Circ
			Preeclampsia (n=35)‡§	A/B	A/B	…	…	P/P	P/P	None	Circ
Microlife WatchBP Home	Chung (2009)	BHS 93 Additional: AAMI	Pregnancy (n=30)‡§	A/A	A/A	…	…	P/P	P/P	None	None
			Preeclampsia (n=15)‡§	B/A	B/A	…	…	P/P	P/P	None	n, comp
Omron HEM 705 CP	Brown (1998)	Nonstandard	Pregnancy (n=50)‡	…	…	…	…	…	…	…	…
	Gupta (1997)	BHS 93 Additional: AAMI	Pregnant w/o preeclampsia (n=85)‡§	B/B	B/B	…	…	F/F	F/F	None	Circ, SBP, DBP
			Preeclampsia (n=42)‡	C/D	C/D	…	…	F/F	F/F	None	Circ, SBP, DBP
	Lo (2002)	Nonstandard	Healthy pregnancy (n=101)‡	…	…	…	…	…	…	…	…
			Preeclampsia (n=45)‡	…	…	…	…	…	…	…	…
Omron M7	De Greeff (2009)	BHS 93 Additional: AAMI	Pregnancy and preeclampsia (n=45)	A/A	A/A	…	…	P/P	P/P	None	Circ#
			Normotensive (n=30)‡§	A/A	A/A	…	…	P/P	P/P	None	Circ#
			Preeclampsia (n=15)‡§	B/B	B/B	…	…	P/P	F/P	n, comp	Circ#
	Nouwen (2012)*	ESH 02 Additional: BHS 93†	Hypertensive preeclampsia (n=33)‡	B/A	B/A (BHS 93) C/B (BHS 90)	F/P	F/P	…	…	None	A, SBP, DBP
Omron MIT	De Greeff (2009)	BHS 93 Additional: AAMI	Pregnancy and preeclampsia (n=45)	A/A	A/A	…	…	P/P	P/P	None	None
			Normotensive (n=30)‡§	A/A	A/A	…	…	P/P	P/P	None	None
			Preeclampsia (n=15)‡§	A/A	A/A	…	…	P/P	P/P	n, comp	None
Omron MIT Elite	Chung (2012)*	BHS 93 Additional: AAMI	Pregnancy and preeclampsia (n=45)	A/A	A/A	…	…	P/P	P/P	None	SBP, DBP
			Normotensive (n=30)‡§	A/A	A/A	…	…	P/P	P/P	None	None
			Preeclampsia (n=15)‡§	A/A	A/A	…	…	P/P	P/P	None	n, comp
	James (2017)¶	BHS 93	Pregnancy with arm circumference >=32 cm (n=46)‡	D/D	C/D	…	…	…	…	None	None
Omron T9P	Brown (2011)*	BHS 90 Additional: AAMI	Pregnancy (n=85)‡§	A/A‖	A/A (BHS 93) B/B (BHS 90)	…	…	P/P	P/P	G‖	SBP, DBP
Takeda UA-751	Brown (1991)	Nonstandard	Pregnancy (n=79)‡	…	…	…	…	…	…	…	…
Withings BP-800	Hay (2016)	BHS 93	Normotensive, hypertensive, and preeclampsia (n=47)‡	C/B	C/B	…	…	…	…	None	None

When >1 protocol is listed, the first protocol is the methodology followed for the validation study and additional protocols are listed when their grading criteria were applied to the data. A indicates age; Adj, adjudicated grade; BP, blood pressure; Circ, arm circumference; comp, number of BP comparisons; DBP, diastolic blood pressure range; G, final grade; n, number of participants; NG, not able to adjudicate a grade; NR, not reported; Obs, observer measurements simultaneous/sequential; Pub, published grade; SBP, systolic blood pressure range; T, trimester; and timing, device vs mercury simultaneous/sequential.

*Authors state device can be used for home or clinical use (data is also found in Table 3).

†Protocol modification: BHS 90 protocol cited in references, but BHS 93 grading was used.

‡Individual studies in the population column.

§Studies that passed the primary protocol.

#Two devices, the MIT and M7, were tested in the same group of women. The MIT can accommodate an arm circumference of 22–32 cm and the M7 can accommodate up to 42 cm. Only women with an arm circumference of 22–32 cm were included in the validation studies.

¶Authors do not specify device type, so prior authors' designation followed (data is also found in Table 3).

‖Protocol modification: BHS 90 protocol was followed but BHS 93 grading was used.

Table 3. Validation Studies of Clinic Devices

Device	First Author (Year)	Protocol(s)	Population (n)	BHS Grade (SBP/DBP)		ESH Grade (SBP/DBP)		AAMI Grade (SBP/DBP)		Violations	
				Pub	Adj	Pub	Adj	Pub	Adj	Major	Minor
Acutorr III	Quinn (1994)	Nonstandard	Normotensive (n=40)*	…	…	…	…	…	…	…	…
			Preeclampsia (n=17)*	…	…	…	…	…	…	…	…
A&D UM-101	Davis (2015)	BHS 93	Normotensive (n=85)*†	A/A	A/A	…	…	…	…	None	None
			Hypertensive (n=85)*†	A/A	A/A	…	…	…	…	None	None
Dinamap 1846	Hasan (1993)	Nonstandard	Pregnancy (n=28)*	…	…	…	…	…	…	…	…
Dinamap 1846SX	Franx (1994)	BHS 90 Additional: AAMI	Pregnancy (n=32)*	C/D	NG	…	…	F/F	F/F	n, comp, timing	SBP,DBP
	Green (1996)	AAMI	Pregnancy (n=81)*	…	…	…	…	F/NR	F/NG	n, comp	SBP,DBP
	Marx (1991)	Nonstandard	Pregnancy (n=20)*	…	…	…	…	…	…	…	…
	Marx (1993)	Nonstandard	Pregnancy (n=12)*	…	…	…	…	…	…	…	…
Dinamap 1846SX/p	Pomini (2001)	BHS 90	Normotensive (n=not specified)*	C/C	C/C	…	…	…	…	n	SBP,DBP
Dinamap ProCare 400	De Greeff (2010)	BHS 93 Additional: AAMI	Pregnancy without preeclampsia (n=30)*†	A/A	A/A	…	…	P/P	P/P	None	None
			Preeclampsia (n=15)*†	A/B	A/B	…	…	P/F	P/F	n, comp	None
Microlife 3AS1-2	Nathan (2015)	BHS 93 Additional: AAMI	Pregnancy and preeclampsia (n=45)*†	B/A	B/A	…	…	P/P	P/P	None	SBP,DBP
	Nathan (2015)	BHS 93 Additional: AAMI	Hypotensive (n=30)*†	A/A	A/A	…	…	P/P	P/P	None	SBP,DBP
Microlife 3BTO-A	Nouwen (2012)‡	ESH 02 Additional: BHS 93‖	Hypertensive preeclampsia (n=33)*†	B/B	B/B (BHS 93) C/C (BHS 90)	F/F	F/F	…	…	None	A, SBP, DBP
Nissei DS-400	De Greeff (2015)	BHS 93 Additional: AAMI	Pregnancy and preeclampsia (n=45)*†	A/A	A/A	…	…	P/P	P/P	None	None
Omron HEM907	Davis (2015)	BHS 93	Normotensive (n=85)*†	A/A	A/A	…	…	…	…	None	None
			Hypertensive (n=85)*†	A/A	A/A	…	…	…	…	None	None
Omron HEM-7200	Lan (2014)	Nonstandard	Pregnancy (n=89)*	…	…	…	…	…	…	…	…
Omron M7	Nouwen (2012)‡	ESH 02 Additional: BHS 93‖	Hypertensive preeclampsia (n=33)*	B/A	B/A (BHS 93) C/B (BHS 90)	F/P	F/P	…	…	None	A, SBP, DBP
Omron MIT	Golara (2002)	BHS 93 Additional: AAMI	Normotensive (n=38)*†	B/A	B/A	…	…	P/P	P/P	None	Circ, T, SBP, DBP
			Preeclampsia (n=15)*†	B/A	B/A	…	…	P/P	P/P	n, comp	Circ, T, SBP, DBP
Omron MIT Elite	Chung (2012)‡	BHS 93 Additional: AAMI	Pregnancy and preeclampsia (n=45)	A/A	A/A	…	…	P/P	P/P	None	SBP, DBP
			Normotensive (n=30)*†	A/A	A/A	…	…	P/P	P/P	None	None
			Preeclampsia (n=15)*†	A/A	A/A	…	…	P/P	P/P	None	n, Comp
	James (2017)§	BHS 93	Pregnancy with arm circumference >=32 cm (n=46)*	D/D	C/D	…	…	…	…	None	None
Omron T9P	Brown (2011)‡	BHS 90 Additional: AAMI	Pregnancy (n=85)*†	A/A¶	A/A (BHS 93) B/B (BHS 90)	…	…	P/P	P/P	G¶	SBP,DBP
Terumo ES-H51	Kewk (1998)	BHS 90	Pregnancy (n=87)*†	A/A	A/A	…	…	…	…	None	SBP,DBP

(*Continued*)

Table 3. Continued

Device	First Author (Year)	Protocol(s)	Population (n)	BHS Grade (SBP/DBP)		ESH Grade (SBP/DBP)		AAMI Grade (SBP/DBP)		Violations	
				Pub	Adj	Pub	Adj	Pub	Adj	Major	Minor
Welch Allyn Vital Signs	Reinders (2003)	BHS 93 Additional: AAMI	Normotensive (n=31)*†	A/A	A/A	…	…	P/P	P/P	None	Circ
			Preeclampsia (n=17)*	D/B	D/B	…	…	F/F	F/F	n, comp	Circ
Welch Allyn Vital Signs 300	Nzelu (2017)	ESH 10	Normotensive, hypertensive, and preeclampsia (n=33)*	…	…	F/F	F/F	…	…	None	A, SBP, DBP

When >1 protocol is listed, the first protocol is the methodology followed for the validation study and additional protocols are listed when their grading criteria were applied to the data. A indicates age; Adj, adjudicated grade; BP, blood pressure; Circ, arm circumference; comp, number of BP comparisons; DBP, diastolic blood pressure range; G, final grade; n, number of participants; NG, not able to adjudicate a grade; NR, not reported; Obs, observer measurements simultaneous/sequential; Pub, published grade; SBP, systolic blood pressure range; T, trimester; and timing, device vs mercury simultaneous/sequential.

*Individual studies in the population column.

†Studies that passed the primary protocol.

‡Authors state device can be used for home or clinical use (data is also found in Table 2).

§Authors do not specify device type, so prior authors' designation followed (data is also found in Table 2).

||Protocol Modification: BHS 90 protocol cited in references, but BHS 93 grading was used.

¶Protocol Modification: BHS 90 protocol was followed, but BHS 93 grading was used.

which are also recommended for home use, passed the validation criteria. None of the 17 studies testing ambulatory, home, or clinic BP devices among pregnant women with preeclampsia was performed without a protocol violation.

The finding that many studies wherein devices were validated had protocol violations is consistent with published studies conducted in nonpregnant women and men.[18,27,72,73] In a systematic review of BP devices validated using the ESH-IP, Stergiou et al[18] found protocol violations in 23 of 78 studies. Similarly, Hodgkinson et al[27] found that of 28 validation studies of ambulatory devices performed in a general adult population, 42%, 11%, and 0% that followed the ESH-IP, AAMI, and BHS, respectively, adhered to the specified protocol without violations. The proper execution of a BP device validation study with strict adherence to the specified protocol is a complex undertaking with several opportunities for violation which may lead to improper performance and result in a detrimental effect on the study's power.[74] All violations, whether classified as major or minor,[18,27] have the potential to effect the results of a validation study, and when noted the results of a validation study should be interpreted with caution.

Table 4. Blood Pressure Measurement Devices Successfully Validated Without Violation in At Least 1 Study of Pregnant Women

Device Type	Device	Study Population
Ambulatory	BP Lab[28]	Normotensive (without preeclampsia) and hypertensive (with and without preeclampsia)
	Welch Allyn QuietTrak[60]	Normotensive and hypertensive
Home	Microlife WatchBP Home[32]	Normotensive and hypertensive, without preeclampsia
	Omron MIT[35]	Normotensive and hypertensive, without preeclampsia
Clinic	A&D UM-101[34]	Normotensive (without preeclampsia) and hypertensive (with and without preeclampsia)
	Dinamap ProCare 400[36]	Normotensive and hypertensive, without preeclampsia
	Nissei DS-400[37]	Normotensive and hypertensive, with and without preeclampsia
	Omron HEM907[34]	Normotensive (without preeclampsia) and hypertensive (with and without preeclampsia)
Home/Clinic	Omron MIT Elite[33]	Normotensive and hypertensive, without preeclampsia

Standardized validation protocols (AAMI, BHS, and ESH-IP) were developed to demonstrate statistical equivalence between new devices and the gold standard mercury sphygmomanometer.[19] Although the ESH-IP was designed to simplify validation studies and has been the most widely used protocol since 2006 among nonpregnant women and men,[18] some have questioned whether it is sufficiently powered to demonstrate equivalence.[18,19] In the current systematic review, 3 articles (testing 4 devices)[28,57,58] used the ESH-IP as the primary validation protocol. The BPLab ambulatory monitor[28] was the only 1 of the 4 devices to pass the ESH-IP in pregnant women. The Microlife 3BTO-A, Omron M7, and Welch Allyn Vital Signs 300 failed the ESH-IP validation.[57,58] Ongoing efforts by an AAMI-ESH-ISO collaboration to create a standardized sufficiently powered universal protocol that will replace all previous protocols should simplify the performance and analysis of future device validation studies among both nonpregnant and pregnant populations.[74]

A strength of the current study is the use of a comprehensive search strategy of multiple databases and websites and the manual review of reference lists of all included articles, without limitations on language. Additionally, we evaluated the available validation data on ambulatory, home, and clinic devices. Data from systematic reviews of the validation of BP devices in pregnant women are sparse, and the results of our study address important knowledge gaps in this area.

However, the current review has several known and potential limitations. First, we excluded studies (n=18) that used a reference device other than a standard mercury sphygmomanometer (Table S4). Although this approach may exclude potentially important studies, the majority of validation protocols require mercury sphygmomanometer as the reference standard,[10,11,15,16] with the exception being the ANSI/AAMI/ISO which has an alternative direct intra-arterial reference option.[12–14] Second, we cannot exclude the possibility of publication bias. Although we found many published studies describing device validation failures, there may be situations in which validation failures were not published. Additionally, although several studies tested the same device, we did not attempt to perform a meta-analysis because of the small number of studies in which these devices were validated without protocol violations. Last, for the 11 studies that followed a nonstandard validation protocol,[24,25,29,30,49–53] we were unable to adjudicate grades or assess violations and cannot comment on the validity of the devices examined. The majority of devices included in this review were oscillometric and use proprietary algorithms to calculate SBP and DBP. Without knowledge of the algorithms, further evaluation of the strengths and weaknesses of the performance of an individual device compared with another is limited.

Perspectives

In the current systematic review, a majority of validation studies examining BP measurement devices in pregnancy had violations. Of the 28 devices examined, 2 ambulatory devices (BP Lab[28] and Welch Allyn QuietTrak[60]), 2 home devices (Microlife WatchBP Home[32] and Omron MIT[35]), 4 clinic BP devices (A&D UM-101,[34] Dinamap ProCare 400,[36] Nissei DS-400,[37] and Omron HEM907[34]), and 1 home/clinic device (Omron MIT Elite[33]) passed a validation study in at least 1 population of pregnant women without any protocol violations. As results from validation studies not adhering to the protocol specifications or those without sufficient power cannot be assumed to be valid, future validation studies of devices in pregnant women are needed to ensure the accurate measurement of BP in pregnancy. Given the potential consequences of inaccurate BP measurement in pregnant women, healthcare providers should use BP devices that have been proven accurate and valid in this population.

Sources of Funding

This study was supported by the National Center for Advancing Translational Sciences, National Institutes of Health (NIH) UL1TR001873 (N.A. Bello), K24-HL125704 from the NIH/National Heart Lung and Blood Institute (D. Shimbo), and 15SFRN2390002 from the American Heart Association (S. Oparil, P. Muntner, D. Shimbo).

Disclosures

D. Shimbo is a consultant for Abbott Vascular and Novartis Pharmaceuticals Corporation.

References

1. American College of Obstetricians and Gynecologists; Task Force on Hypertension in Pregnancy. Hypertension in pregnancy. Report of the American College of Obstetricians and Gynecologists' Task Force on Hypertension in Pregnany. *Obstet Gynecol*. 2013;122:1122–1131. doi: 10.1097/01.AOG.0000437382.03963.88.
2. Harper LM, Biggio JR, Anderson S, Tita AT. Gestational age of delivery in pregnancies complicated by chronic hypertension. *Obstet Gynecol*. 2016;127:1101–1109. doi: 10.1097/AOG.0000000000001435.
3. Roberts JM, Pearson GD, Cutler JA, Lindheimer MD; National Heart Lung and Blood Institute. Summary of the NHLBI working group on research on hypertension during pregnancy. *Hypertens Pregnancy*. 2003;22:109–127. doi: 10.1081/PRG-120016792.
4. Berg CJ, Mackay AP, Qin C, Callaghan WM. Overview of maternal morbidity during hospitalization for labor and delivery in the United States: 1993-1997 and 2001-2005. *Obstet Gynecol*. 2009;113:1075–1081. doi: 10.1097/AOG.0b013e3181a09fc0.
5. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol*. 2012;120:1029–1036. doi: 10.1097/AOG.0b013e31826d60c5.
6. Creanga AA, Berg CJ, Syverson C, Seed K, Bruce FC, Callaghan WM. Pregnancy-related mortality in the United States, 2006-2010. *Obstet Gynecol*. 2015;125:5–12. doi: 10.1097/AOG.0000000000000564.
7. Magee LA, von Dadelszen P, Rey E, et al. Less-tight versus tight control of hypertension in pregnancy. *N Engl J Med*. 2015;372:407–417. doi: 10.1056/NEJMoa1404595.
8. SMFM Publications Committee. SMFM Statement: benefit of antihypertensive therapy for mild-to-moderate chronic hypertension during pregnancy remains uncertain. *Am J Obstet Gynecol*. 2015;213:3–4. doi: 10.1016/j.ajog.2015.04.013.
9. Chronic Hypertension and Pregnancy (CHAP) Project. https://clinicaltrials.gov/ct2/show/NCT02299414?term=chap&rank=3. Accessed June 30, 2017.
10. O'Brien E, Petrie J, Littler WA, De Sweit M, Padfield PL, Altman D, Bland M, Coats A, Atkins N. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. *J Hypertens*. 1993;11:677–679.
11. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Press Monit*. 2010;15:23–38. doi: 10.1097/MBP.0b013e3283360e98.
12. Association for the Advancement of Medical Instrumentation. *American National Standard. Electronic or automated sphygmomanometers ANSI/AAMI SP10-1987*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 1987.
13. Association for the Advancement of Medical Instrumentation. *American National Standard. Manual, electronic or automated sphygmomanometers ANSI/AAMI SP10-2002/A1*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2003.
14. Association for the Advancement of Medical Instrumentation. *American National Standard. ANSI/AAMI/ISO 81060–2:2013 Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013.
15. O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, Altman DG, Bland M, Coats A, Atkins N. An outline of the revised British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens*. 1993;11:677–679.
16. O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, O'Malley K, Jamieson M, Altman D, Bland M, Atkins N. The British Hypertension Society protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens*. 1990;8:607–619.
17. O'Brien E. Proposals for simplifying the validation protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation. *Blood Press Monit*. 2000;5:43–45.
18. Stergiou GS, Karpettas N, Atkins N, O'Brien E. European Society of Hypertension International Protocol for the validation of blood pressure monitors: a critical review of its application and rationale for revision. *Blood Press Monit*. 2010;15:39–48. doi: 10.1097/MBP.0b013e3283360eaf.
19. Friedman BA, Alpert BS, Osborn D, Prisant LM, Quinn DE, Seller J. Assessment of the validation of blood pressure monitors: a statistical reappraisal. *Blood Press Monit*. 2008;13:187–191. doi: 10.1097/MBP.0b013e3283071a64.
20. The Cochrane Collaboration. In: Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0*. The Cochrane Collaboration, 2011. http://handbook.cochrane.org.

21. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA; PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015;4:1. doi: 10.1186/2046-4053-4-1.
22. Helewa ME, Burrows RF, Smith J, Williams K, Brain P, Rabkin SW. Report of the Canadian Hypertension Society Consensus Conference: 1. Definitions, evaluation and classification of hypertensive disorders in pregnancy. *CMAJ*. 1997;157:715–725.
23. National High Blood Pressure Education Program Working Group on High Blood Pressure in Pregnancy. Report of the National High Blood Pressure Education Program Working Group on high blood pressure in pregnancy. *Am J Obstet Gynecol*. 2000;183:S1–S22.
24. Hasan MA, Thomas TA, Prys-Roberts C. Comparison of automatic oscillometric arterial pressure measurement with conventional auscultatory measurement in the labour ward. *Br J Anaesth*. 1993;70:141–144.
25. Quinn M. Automated blood pressure measurement devices: a potential source of morbidity in preeclampsia? *Am J Obstet Gynecol*. 1994;170(5 pt 1):1303–1307.
26. O'Brien E, Atkins N, Staessen J. State of the market. A review of ambulatory blood pressure monitoring devices. *Hypertension*. 1995;26:835–842.
27. Hodgkinson JA, Sheppard JP, Heneghan C, Martin U, Mant J, Roberts N, McManus RJ. Accuracy of ambulatory blood pressure monitors: a systematic review of validation studies. *J Hypertens*. 2013;31:239–250. doi: 10.1097/HJH.0b013e32835b8d8b.
28. Bartosh LF, Dorogova JV, Kuznecova TN, Krylova AV. The testing of BPLab Ambulatory Blood Pressure Monitor on the pregnant in conformity with International Protocol of the European Society of Hypertension (ESH-2001). *Arterial Hypertension.TOM*. 2006;12:3–6.
29. Brown MA, Adsett D. Automated blood-pressure recording in pregnancy. *Clin Exp Hypertens*. 1991;10:7–19.
30. Brown MA, Robinson A, Buddle ML. Accuracy of automated blood pressure recorders in pregnancy. *Aust N Z J Obstet Gynaecol*. 1998;38:262–265.
31. Brown MA, Roberts L, Davis G, Mangos G. Can we use the Omron T9P automated blood pressure monitor in pregnancy? *Hypertens Pregnancy*. 2011;30:188–193. doi: 10.3109/10641955.2010.507854.
32. Chung Y, de Greeff A, Shennan A. Validation and compliance of a home monitoring device in pregnancy: microlife WatchBP home. *Hypertens Pregnancy*. 2009;28:348–359. doi: 10.1080/10641950802601286.
33. Chung Y, Brochut MC, de Greeff A, Shennan AH. Clinical accuracy of inflationary oscillometry in pregnancy and pre-eclampsia: Omron-MIT Elite. *Pregnancy Hypertens*. 2012;2:411–415. doi: 10.1016/j.preghy.2012.04.001.
34. Davis GK, Roberts LM, Mangos GJ, Brown MA. Comparisons of auscultatory hybrid and automated sphygmomanometers with mercury sphygmomanometry in hypertensive and normotensive pregnant women: parallel validation studies. *J Hypertens*. 2015;33:499–505; discussion 505. doi: 10.1097/HJH.0000000000000420.
35. de Greeff A, Beg Z, Gangji Z, Dorney E, Shennan AH. Accuracy of inflationary versus deflationary oscillometry in pregnancy and preeclampsia: OMRON-MIT versus OMRON-M7. *Blood Press Monit*. 2009;14:37–40. doi: 10.1097/MBP.0b013e32831e305d.
36. De Greeff A, Ghosh D, Anthony J, Shennan A. Accuracy assessment of the Dinamap ProCare 400 in pregnancy and preeclampsia. *Hypertens Pregnancy*. 2010;29:198–205. doi: 10.3109/10641950902968650.
37. de Greeff A, Shennan AH. Clinical accuracy of a low cost portable blood pressure device in pregnancy and pre-eclampsia: the Nissei DS-400. *Trop Doct*. 2015;45:168–173. doi: 10.1177/0049475515581542.
38. Dorogova IV, Panina ES. Comparison of the BPLab® sphygmomanometer for ambulatory blood pressure monitoring with mercury sphygmomanometry in pregnant women: validation study according to the British Hypertension Society protocol. *Vasc Health Risk Manag*. 2015;11:245–249. doi: 10.2147/VHRM.S82381.
39. Elvan-Taşpinar A, Uiterkamp LA, Sikkema JM, Bots ML, Koomans HA, Bruinse HW, Franx A. Validation and use of the Finometer for blood pressure measurement in normal, hypertensive and pre-eclamptic pregnancy. *J Hypertens*. 2003;21:2053–2060. doi: 10.1097/01.hjh.0000098138.70956.68.
40. Franx A, van der Post JA, Elfering IM, Veerman DP, Merkus HM, Boer K, van Montfrans GA. Validation of automated blood pressure recording in pregnancy. *Br J Obstet Gynaecol*. 1994;101:66–69.
41. Franx A, van der Post JA, van Montfrans GA, Bruines HW. Comparison of an Auscultatory versus an oscillometric ambulatory blood pressure monitor in normotensive, hypertensive, and preeclamptic pregnancy. *Hypertens Pregnancy*. 1997;16:187–202.
42. Golara M, Benedict A, Jones C, Randhawa M, Poston L, Shennan AH. Inflationary oscillometry provides accurate measurement of blood pressure in pre-eclampsia. *BJOG*. 2002;109:1143–1147.
43. Green LA, Froman RD. Blood pressure measurement during pregnancy: auscultatory versus oscillatory methods. *J Obstet Gynecol Neonatal Nurs*. 1996;25:155–159.
44. Gupta M, Shennan AH, Halligan A, Taylor DJ, de Swiet M. Accuracy of oscillometric blood pressure monitoring in pregnancy and pre-eclampsia. *Br J Obstet Gynaecol*. 1997;104:350–355.
45. Hay A, Ayis S, Nzelu D, James L, Kametas NA. Validation of the Withings BP-800 in pregnancy and impact of maternal characteristics on the accuracy of blood pressure measurement. *Pregnancy Hypertens*. 2016;6:406–412. doi: 10.1016/j.preghy.2016.09.005.
46. James L, Nzelu D, Hay A, Shennan A, Kametas NA. Validation of the Omron MIT Elite blood pressure device in a pregnant population with large arm circumference. *Blood Press Monit*. 2017;22:109–111. doi: 10.1097/MBP.0000000000000239.
47. Koenen SV, Franx A, Oosting H, Bonsel GJ, Bruinse HW, Visser HA. Within-subject variability of differences between conventional and automated blood pressure measurements in pregnancy. *Eur J Obstet Gynecol Reprod Biol*. 1998;80:79–84.
48. Kwek K, Chan YG, Tan KH, Yeo GS. Validation of an oscillometric electronic sphygmomanometer in an obstetric population. *Am J Hypertens*. 1998;11(8 pt 1):978–982.
49. Lan PG, Clayton PA, Hyett J, Gillin AG. Measuring blood pressure in pregnancy and postpartum: assessing the reliability of automated measuring devices. *Hypertens Pregnancy*. 2014;33:168–176. doi: 10.3109/10641955.2013.843007.
50. Lo C, Taylor RS, Gamble G, McCowan L, North RA. Use of automated home blood pressure monitoring in pregnancy: is it safe? *Am J Obstet Gynecol*. 2002;187:1321–1328.
51. Marx GF, Sofair DR, Winikoff SI. Blood pressure values in parturients: auscultatory versus oscillatory values. *Anesth Analg*. 1991;72:562–563.
52. Marx GF, Schwalbe SS, Cho E, Whitty JE. Automated blood pressure measurements in laboring women: are they reliable? *Am J Obstet Gynecol*. 1993;168(3 pt 1):796–798.
53. Montan S, Choolani M, Arulkumaran S, Ratnam SS. Automated 24-hour ambulatory blood pressure monitoring in preeclampsia. *J Perinat Med*. 1995;23:353–358.
54. Natarajan P, Shennan AH, Penny J, Halligan AW, de Swiet M, Anthony J. Comparison of auscultatory and oscillometric automated blood pressure monitors in the setting of preeclampsia. *Am J Obstet Gynecol*. 1999;181(5 pt 1):1203–1210.
55. Nathan HL, de Greeff A, Hezelgrave NL, Chappell LC, Shennan AH. An accurate semiautomated oscillometric blood pressure device for use in pregnancy (including pre-eclampsia) in a low-income and middle-income country population: the Microlife 3AS1-2. *Blood Press Monit*. 2015;20:52–55. doi: 10.1097/MBP.0000000000000086.
56. Nathan HL, de Greeff A, Hezelgrave NL, Chappell LC, Shennan AH. Accuracy validation of the Microlife 3AS1-2 blood pressure device in a pregnant population with low blood pressure. *Blood Press Monit*. 2015;20:299–302. doi: 10.1097/MBP.0000000000000134.
57. Nouwen E, Snijder M, van Montfrans G, Wolf H. Validation of the Omron M7 and Microlife 3BTO-A blood pressure measuring devices in preeclampsia. *Hypertens Pregnancy*. 2012;31:131–139. doi: 10.3109/10641955.2010.544799.
58. Nzelu D, Yeung F, Couderq D, Shennan A, Kametas NA. An inaccurate automated device negatively impacts the diagnosis and treatment of gestational hypertension. *Pregnancy Hypertens*. 2017;22:109–111.
59. O'Brien E, Mee F, Atkins N, Halligan A, O'Malley K. Accuracy of the SpaceLabs 90207 ambulatory blood pressure measuring system in normotensive pregnant women determined by the British Hypertension Society protocol. *J Hypertens Suppl*. 1993;11:S282–S283.
60. Penny JA, Shennan AH, Rushbrook J, Halligan AW, Taylor DJ, De Sweit M. Validation of the Welch Allyn QuietTrak ambulatory blood pressure monitor in pregnancy. *Hypertens Pregnancy*. 1996;15:313–321.
61. Pomini F, Scavo M, Ferrazzani S, De Carolis S, Caruso A, Mancuso S. There is poor agreement between manual auscultatory and automated oscillometric methods for the measurement of blood pressure in normotensive pregnant women. *J Matern Fetal Med*. 2001;10:398–403.
62. Reinders A, Cuckson AC, Jones CR, Poet R, O'Sullivan G, Shennan AH. Validation of the Welch Allyn 'Vital Signs' blood pressure measurement device in pregnancy and pre-eclampsia. *BJOG*. 2003;110:134–138.
63. Reinders A, Cuckson AC, Lee JT, Shennan AH. An accurate automated blood pressure device for use in pregnancy and

pre-eclampsia: the Microlife 3BTO-A. *BJOG*. 2005;112:915–920. doi: 10.1111/j.1471-0528.2005.00617.x.
64. Shennan AH, Kissane J, de Swiet M. Validation of the SpaceLabs 90207 ambulatory blood pressure monitor for use in pregnancy. *Br J Obstet Gynaecol*. 1993;100:904–908.
65. Shennan A, Halligan A, Gupta M, Taylor D, de Swiet M. Oscillometric blood pressure measurements in severe pre-eclampsia: validation of the SpaceLabs 90207. *Br J Obstet Gynaecol*. 1996;103:171–173.
66. Tape TG, Rayburn WF, Bremer KD, Schnoor TA. Ambulatory blood pressure monitoring during pregnancy with a new, small, easily concealed monitor. *J Reprod Med*. 1994;39:968–972.
67. Shennan AH, Halligan AW. Measuring blood pressure in normal and hypertensive pregnancy. *Baillieres Best Pract Res Clin Obstet Gynaecol*. 1999;13:1–26. doi: 10.1053/beog.1999.0003.
68. Nathan HL, Duhig K, Hezelgrave NL, Chappell LC, Shennan AH. Blood pressure measurement in pregnancy. *Obstet Gynaecol*. 2015;17:91–8.
69. Tremonti C, Beddoe J, Brown MA. Reliability of home blood pressure monitoring devices in pregnancy. *Pregnancy Hypertens*. 2017;8:9–14. doi: 10.1016/j.preghy.2017.01.002.
70. Bibbins-Domingo K, Grossman DC, Curry SJ, Barry MJ, Davidson KW, Doubeni CA, Epling JW Jr, Kemper AR, Krist AH, Kurth AE, Landefeld CS, Mangione CM, Phillips WR, Phipps MG, Silverstein M, Simon MA, Tseng CW; US Preventive Services Task Force. Screening for Preeclampsia: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2017;317:1661–1667. doi: 10.1001/jama.2017.3439.
71. Henderson JT, Thompson JH, Burda BU, Cantor A. Preeclampsia screening: evidence report and systematic review for the US Preventive Services Task Force. *JAMA*. 2017;317:1668–1683. doi: 10.1001/jama.2016.18315.
72. Al Hamarneh YN, Houle SK, Chatterley P, Tsuyuki RT. The validity of blood pressure kiosk validation studies: a systematic review. *Blood Press Monit*. 2013;18:167–172. doi: 10.1097/MBP.0b013e328360fb85.
73. Wan Y, Heneghan C, Stevens R, McManus RJ, Ward A, Perera R, Thompson M, Tarassenko L, Mant D. Determining which automatic digital blood pressure device performs adequately: a systematic review. *J Hum Hypertens*. 2010;24:431–438. doi: 10.1038/jhh.2010.37.
74. O'Brien E, Stergiou GS. The pursuit of accurate blood pressure measurement: a 35-year travail. *J Clin Hypertens (Greenwich)*. 2017;19:746–752. doi: 10.1111/jch.13005.

Novelty and Significance

What Is New?

- We have systematically reviewed and summarized the published validation data for ambulatory, home, and clinic blood pressure measurement devices in pregnancy.

What Is Relevant?

- The use of properly validated devices are essential for the accurate measurement of blood pressure and the provision of care to pregnant women at risk for and diagnosed with hypertension.
- As results from validation studies not adhering to the protocol specifications or those without sufficient power cannot be assumed to be valid, healthcare providers should use blood pressure measurement devices that have been proven accurate and valid in this population.

Summary

Of the 28 devices examined, 2 ambulatory devices (BP Lab and Welch Allyn QuietTrak), 2 home devices (Microlife WatchBP Home and Omron MIT), 4 clinic BP devices (A&D UM-101, Dinamap Pro-Care 400, Nissei DS-400, and Omron HEM907), and 1 home/clinic device (Omron MIT Elite) passed a validation study in at least 1 population of pregnant women without any protocol violations. The availability of validated blood pressure measurement devices is increasingly important as the prevalence of hypertensive disorders of pregnancy continues to rise and specialty societies are increasingly recognizing the importance of close monitoring and follow-up of these women.