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3 **Home blood pressure monitoring in the diagnosis and treatment of hypertension in**
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5 **pregnancy: A systematic review and meta-analysis**
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Abstract

Background: Home blood pressure monitoring (HBPM) is commonly used by non-pregnant adults for the diagnosis and management of hypertension. Increasingly, HBPM is used for pregnant women; however, there are no current guidelines on the standardized use of this tool in pregnancy. The objectives of this systematic review and meta-analysis were to assess how HBPM in pregnancy is currently prescribed and to identify home blood pressure (HBP) targets that are equivalent to office blood pressure (OBP) for diagnosis and management of hypertension in pregnancy.

Methods: MEDLINE, Embase and CENTRAL databases were searched (inception-March 2020) for observational studies and randomized controlled trials evaluating HBPM with OBP measurements in pregnant women. We identified 17 studies that assessed HBPM with OBP (N=1603 pregnant women).

Results: We observed wide variation in practice patterns on how HBP was measured in pregnant women. Only one-third of studies utilized validated HBP devices. HBP was measured between 3 to 36 times per week with variable compliance between 11.2-92.0%. Equivalent HBP to OBP of 140/90 mm Hg in the third trimester ranged from 118-143/76-92 mm Hg depending on patient population and methodology. Home SBP and DBP were significantly lower than office by 4.53 (95% CI 2.64-6.41) mm Hg and 3.01 (1.42-4.60) mm Hg, respectively.

Conclusions: Despite the inadvertent adoption of HBPM in pregnant patients, many issues are currently unresolved; these include HBP technique, frequency of monitoring, and targets. Future

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3 studies should prioritize using validated HBP devices, determine standardized HBP measurement
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5 schedules and establish treatment targets.
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Confidential

Introduction:

Out-of-office blood pressure (BP) monitoring, with 24h ambulatory BP monitoring (ABPM) or home BP monitoring (HBPM) is routinely performed in adults for diagnosis and management of hypertension (1-5). Although, ABPM is the gold standard for out-of-office BP measurements, HBPM is easy to use, allows frequent measurements, cost effective, and widely available (6). Home BP (HBP) has better correlation with target end organ damage, and cardiovascular mortality compared with office BP (OBP) (6). For these reasons, hypertension guidelines in Canada and internationally have strongly endorsed HBPM.

Hypertensive disorders of pregnancy (HDP) occur in up to 10% of all pregnancies and are associated with maternal and neonatal morbidity and mortality (7). HBPM is increasingly used as a tool to monitor pregnant patients for the development of HDP (8). Canadian obstetricians, family physicians, obstetrical medicine and maternal fetal medicine specialists frequently recommend HBPM to their pregnant patients (9, 10). However, wide variation in practice on how clinicians recommend HBPM to their pregnant women was noted, highlighting a lack of relevant studies (10).

Despite the widespread use of HBPM in pregnancy, how to best measure home BP (HBP), the thresholds to initiate anti-hypertensive medications, and treatment targets are unclear. Simply extrapolating the experience of HBPM from the general population is problematic. Currently, Canadian guidelines in pregnancy recommend that a HBP mean of 135/85 mm Hg be considered equivalent to OBP mean of 140/90 mm Hg based on evidence in the non-pregnant population (11). This approach, however, has not been validated in the pregnant population. Hemodynamic

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3 changes of pregnancy can lead to reductions in BP, with a nadir at 18-24 weeks; therefore, it is
4 unclear if normal BP thresholds should vary according to different trimesters. Moreover, unlike
5 the non-pregnant population, no data are available to assess maternal and neonatal outcomes with
6 HBP compared with OBP measurements.
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14 Therefore, we sought to systematically evaluate how different investigators derive proposed
15 diagnosed and therapeutic thresholds for HBP and to perform a meta-analysis to compare HBP
16 and OBP measurements in pregnancy.
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24 **Methods:**

25 *Description of search concepts*

26 We conducted a search of the English language using the key words ‘hypertension’, ‘pregnancy’,
27 ‘BP monitoring’, and ‘self-monitoring’ in MEDLINE Ovid (inception to March 2020), Embase
28 Ovid (1974 to March 2020), and CENTRAL Ovid (inception to March 2020). Our systematic
29 review protocol was registered with PROSPERO (CRD4202147352).
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40 *Study Selection*

41 We imported all title and abstract records retrieved by electronic searches into Covidence.
42 Duplicates were automatically removed by Covidence (14). Two reviewers (KT, WSC)
43 independently reviewed all titles and abstracts retrieved from our electronic searches. Our
44 inclusion criteria included pregnant women, use of home and office BP measurements,
45 observational studies, and parallel-group randomized controlled trials. We excluded studies that
46 did not compare home and office BP readings. Two reviewers (KT, WSC) independently
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3 screened full text articles. Any disagreements were resolved by discussion. If multiple full text
4 reports were located for the same study (i.e.: sub-study, extension), all available information
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6 were used to identify the relevant outcomes. We documented the screening of studies during the
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8 systematic review process using a PRISMA flow diagram (15).
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14 ***Data extraction and management***

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16 Study characteristics were extracted from all eligible studies. We collected information regarding
17 brand of HBP monitor, HBP monitoring schedule, patient instructions, mean HBP stratified by
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19 trimester, and upper limit of normal (ULN) of HBP readings defined as mean \pm 2 standard
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21 deviations (SD) or 95th percentile. For OBP measurements, we collected information regarding
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23 brand of OBP measurement device, method of OBP measurements, and mean OBP for different
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25 trimesters.
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33 Two reviewers (KT, WSC) extracted the data independently from eligible studies.

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35 Disagreements were resolved by discussion. To confirm unreported data, study protocols and
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37 supplementary material were reviewed, and study authors were contacted for missing data, up to
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39 three times via email.
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44 ***Assessment of Study Quality***

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46 We assessed study quality using Newcastle-Ottawa Quality Assessment Scale for cohort studies
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48 (NOS). The NOS is based on selection (4 items), comparability (1 item) and outcome (3 items),
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50 and provides a “star scoring system,” which translates into good, fair, or low quality (12).
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3 Quality assessment was performed by two independent reviewers (KT, WSC) and discrepancies
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5 were resolved by discussion.
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10 ***Statistical Analysis***

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12 For each study, we calculated the mean difference and corresponding 95% confidence
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14 intervals (CI) for home and office BP measurements during the third trimester. Meta-
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16 analysis was performed using a random-effects model that include between-study
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18 heterogeneity. Chi squared tests for heterogeneity was used to assess between-study
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20 heterogeneity. Observed heterogeneity was assessed by I^2 , with less than 25% denoting
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22 low heterogeneity. We applied Harbord Egger small study effects analysis to assess for
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24 publication bias. We conducted a sensitivity analysis, where we included studies that
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26 used a validated HBP monitors in the pooled analysis. Analyses were performed using
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28 Review Manager (RevMan, Computer program, Version 5.3. Copenhagen: The Nordic
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30 Cochrane Centre, The Cochrane Collaboration, 2014). All P values are 2-tailed.
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40 **Results:**

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42 Our search strategy yielded 983 unique citations, of which 47 were eligible for full text review.
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44 Of these 47, we excluded 30 articles: 11 did not include HBP measurements, 10 did not use
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46 HBPM as their intervention, 6 did not compare HBP with OBP, 2 were not performed in the
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48 setting of interest, and 1 did not include pregnant women. Seventeen articles from our search
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50 were included in our systematic review (Figure 1). Three of the studies involved the same cohort
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52 of patients, Babies and their Parents' Longitudinal Observation in Suzuki Memorial Hospital on
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3 Intrauterine Period (BOSHI) study, and data specific for the clinical outcomes was extracted
4 from all studies, avoiding duplication (13-15). Therefore, 15 studies were used in the final
5 analysis, with a total number of 1689 pregnant participants. Using NOS quality assessment, most
6 studies were judged to be fair (16-24) and good quality (13-15, 25, 26), while 3 studies were
7 deemed poor quality (27-29) and high risk of bias.
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17 ***Study Characteristics***

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19 Studies were published from 1987 to 2019, and all recruited patients from antenatal maternity
20 clinics. The studies included pregnant patients who were normotensive (N=8), had chronic
21 hypertension (N=2), hypertensive disorders of pregnancy (N=5), high risk of preeclampsia (N=1)
22 and isolated office hypertension (N=2). Study characteristics are summarized in Table 1.
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31 ***Patient education and monitoring***

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33 Fourteen out of the 15 studies provided either verbal or written instructions to participants on
34 how to monitor HBP. Three studies used telemonitoring (21, 27, 29) or medical apps (25) to
35 transmit HBP measurements to clinicians. Four studies provided patient instructions on when to
36 seek medical advice for their hypertension (19, 22, 23, 25). These triggering BP values were
37 variable: $\geq 140/90$ mm Hg with proteinuria or $\geq 160/100$ mm Hg without proteinuria (19); SBP
38 ≥ 155 mm Hg or DBP ≥ 100 mm Hg (25); and $\geq 140/90$ mm Hg or $\leq 100/60$ mm Hg (23). Tucker
39 et al implemented a colour coded pamphlet with detailed instructions and follow up (22).
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51 ***Device selection and validation***

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3 Six out of 15 (40.0%) studies used a validated HBP monitor approved for pregnancy (Microlife
4 Watch BP, Microlife 3A Plus, Omron HEM705CP) (19, 22-26), with Microlife Watch BP
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6 (26.7%) being the most common.
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11 ***Frequency and timing of HBPM***

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14 Frequency and timing of BP measurements varied among studies. Overall, HBP was measured
15 between 1 to 6 times per day and 1 to 7 times per week. Measuring BP twice in the morning and
16 evening for 1 week was the most common method described (26.7%). The total number of
17 measurements recorded per week ranged from 3 to 36. Only one study discarded the first day's
18 readings prior to averaging the results (23).
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28 ***Diagnostic Thresholds for HBP Measurements***

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30 Five studies calculated the diagnostic thresholds for HBP by applying the HBP data a relative
31 metric derived from the OBP data of that sample (16, 17, 20, 21, 26). Depending on the method
32 used, the identified HBP diagnostic threshold for the third trimester was 138/88 mm Hg (2 SD
33 cut-off) (16), 143/92 mm Hg (90th percentile cut-off) (17), 121/80 mm Hg (2 SD cut-off) (20),
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35 118/76 mm Hg (95th percentile cut-off) (20), 136/89 mm Hg (regression line from standardized
36 major axis methods cut-off) (21), and 123/78 (2 SD cut-off) (26). Proposed diagnostic thresholds
37 for HBPM varied by patient population, methodology, and trimester (Table 2). HBP thresholds
38 were lower in the first and second trimester compared with the third trimester. Furthermore, in
39 studies that enrolled subjects without HDP (20, 26), HBP thresholds were lower than studies who
40 enrolled women with chronic hypertension or HDP (16, 17, 21).
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Comparison between HBP and OBP Measurements

Aggregate data meta-analysis of 11 studies (N=1290 pregnant women) for BP differences between home and office during the third trimester was performed (Figure 2). HBP was noted to be significantly lower than OBP for SBP and DBP by 4.53 (95% CI 2.64-6.41) mm Hg and 3.01 (95% CI 1.42-4.60) mm Hg, respectively. Sensitivity analysis showed similar results for SBP and DBP when comparing studies (N=4) when validated HBP monitors for pregnancy were used (Figure 3). The mean difference between home and office BP using validated HBP monitors for SBP and DBP was 4.89 (95% CI 0.95-8.83) mm Hg and 4.56 (95% CI 1.06-8.06) mm Hg, respectively. Significant heterogeneity was observed in the meta-analysis with I^2 ranging from 83 to 93%. Furthermore, asymmetry was noted in the Harbord Egger small study effects funnel plots, hence suggesting publication bias.

Relationship of HBP measurements to outcomes

No differences in maternal or fetal outcomes were reported between HBPM and usual care in maternity day unit, however, this study was not powered to detect these differences (25). HBPM was associated with reduction in hypertension related visits (6.5 visits vs. 8 visits, $p=0.003$) (25). Post intervention surveys among pregnant women, illustrated that HBPM was easy to use (29, 30). HBPM changed management plans for 10% of patients in one study, but almost 50% of patients did not follow instructions properly (19).

Compliance in performing HBP measurements

Compliance to HBPM was reported in 3 studies (15, 19, 23). Iwama *et al* noted that only 9.4% of participants measured their BP daily (15). In contrast, Chung *et al* observed that 81% of

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3 participants measured their BP daily for 1 week. (19). Similarly, Lan *et al* noted that 92% of all
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5 patients had greater than 12 home readings over 3 days (23).
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10 **Discussion**

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12 Despite increased adoption of HBPM in the management of pregnant women with hypertension,
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14 deriving an evidence-based approach from the current literature is difficult. Most studies were
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16 not performed using validated devices for pregnancy. Nearly all HBP devices interpret an
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18 oscillometric signal, which may be altered in pregnancy because of changes in vascular
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20 compliance, intravascular volume, and vascular wall edema. This can reduce the oscillometric
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22 signal and underestimate BP (27, 28). Use of non-validated BP devices can under-diagnoses and
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24 under-treat of HDP by 48% and 80%, respectively (31). Furthermore, in a real-world setting, few
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26 pregnant patients use a validated HBP monitor, and even fewer use a validated HBP monitor
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28 specific for pregnancy (32). This may stem from few validated HBP monitors for pregnancy
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30 exist (33), limited availability, costs, and lack of knowledge of clinicians on brands of validated
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32 HBP monitors for pregnancy.
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40 Second, the methodology used to determine HBP varied amongst studies. Between 3-36 HBP
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42 readings per week were used to calculate average HBP, and no studies derived prognostic or
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44 outcome algorithms based on these readings. Similarly in non-pregnant population, compliance
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46 with HBPM was noted to worsen when patients are asked to monitor for a longer time period
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48 with greater frequency (34). Even when clear instructions were provided to patients, instructions
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50 were only followed correctly half the time (20). In order to have accurate HBP measurements,
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52 patient education is vital. From the non-pregnant population, a minimum of 12 BP readings is
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3 needed for HBPM to be valid (6), and more recently 3 days of BP readings appeared sufficient to
4 prognostic HBP readings (35). A pragmatic HBP monitoring schedule is necessary to balance
5 valid HBP readings with patient compliance.
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12 From our systematic review, we observed that the proposed diagnostic thresholds for
13 hypertension in the third trimester of pregnancy varied substantially across studies, ranging from
14 SBP 118 to 143 mm Hg and DBP 76 to 92 mm Hg (18, 24-26). This is because of patient
15 heterogeneity and methods used to derive thresholds (18, 24-26). Instead of deriving diagnostic
16 thresholds using relative metrics from OBP data, it would be preferable to collect high-quality
17 prognostic data to determine HBP thresholds at which the risk of clinically important
18 complications begin to rise.
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31 An individual patient data meta-analysis by Tucker et al (36) on home and clinic BP
32 measurements in pregnant women similarly highlighted these limitations. Our meta-analysis
33 differs from Tucker et al as they reported no differences between home and clinic BP
34 measurements (mean differences SBP and DBP of 1.5-2.2 mm Hg and 0.7-1.5 mm Hg,
35 respectively) (36). Significant heterogeneity in the data ($I^2 > 80\%$) was noted, which suggests
36 significant variability in study design, population, and methodology of HBP measurements. Use
37 of aggregate data versus individual patient data meta-analysis, inclusion of the BOSHI study
38 (N=530 pregnant women), and publication bias may account for the differences in our results.
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40 Given the large heterogeneity of these two meta-analysis secondary to variability in study design,
41 patient selection and HBP devices used warrants further forethought before clinical
42 implementation that home and clinic BP are equivalent.
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5 Kalafat et al noted in their systematic review and meta-analysis that antenatal use of HBPM
6 reduced risk of induction of labour (OR: 0.55, 95% CI: 0.36-0.88), prenatal hospital admissions
7 (OR 0.31, 95% CI: 0.19-0.49), and diagnosis of preeclampsia (OR:0.50, 95% CI: 0.31-0.81), and
8 number of antenatal visits (standard mean difference -0.49, 95% CI: -0.82 to -0.16). However,
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10 significant clinical heterogeneity, low quality of evidence, and small sample size, are significant
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12 limitations to this study (37).
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21 The strengths of our systematic review were adopting rigorous criteria to assess how HBP was
22 used in pregnant patients (6), which allowed us to systematically review the process of how HBP
23 was being prescribed in pregnancy. Limitations include lack of randomized controlled trials and
24 outcome data for HBPM in pregnancy. Publication bias and small study size may influence the
25 effect size of the differences between HBP and OBP measurements. At least one-third of
26 the patients were from the BOSHI study and therefore, it may skew the data towards
27 their study results. Furthermore, amongst the studies assessed, the rigor of how HBPM
28 was conducted was low, especially in terms of using validated home BP devices,
29 inadequate patient education, and lack of standardized HBPM schedule. Poor data
30 quality can influence the interpretation of this meta-analysis. Therefore, future studies
31 with strong emphasis on the rigorous use of HBPM in pregnancy are needed.
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52 Nevertheless, HBPM is an important tool when managing women with HDP. HBPM is vital in
53 detecting rapid and acute BP changes especially when pre-eclampsia develops. Qualitative
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3 analysis from these studies also showed that patients described clinical benefit with HBPM with
4 decreased need for antenatal visits (22), timely adjustments of anti-hypertensive medications
5 (21), and ease of use (17).
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12 HBPM has potential to revolutionize care of pregnant women with hypertension. However,
13 based on current studies, the implementation of HBPM is uncertain. Future studies evaluating
14 HBP monitors for HDP, should use validated devices, collect reference data in health pregnant
15 samples, use guideline concordant HBPM schedules, define diagnostic and treatment thresholds
16 based on HBP measurements, and collect outcome data.
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26 **Conclusions:**

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28 Although HBPM is increasingly used in pregnancy, current studies do not provide adequate
29 guidance with respect to the use of HBPM in pregnant patients. Future studies are needed and
30 these should focus on defining diagnostic and treatment thresholds for HBP and clarifying the
31 relationship between HBPM and clinically important outcomes.
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Table 1: Summary of home blood pressure monitoring studies in pregnancy

Author	Year	Country	Setting	Population	Sample size	Mean age (years)	Baseline mean Office BP (mm Hg)	Brand of HBPM	Validated for use in pregnancy	Number of BP measurements per week
Dalton (27)	1987	United Kingdom	Antenatal Clinic	HDP	10	28-39	136±17/ 83±8	Dinamap 1846	No	4-28
Mooney (28)	1991	United Kingdom	Antenatal Clinic	1-2 high BP readings	35	NA	139±13/ 74 ±10	Dinamap 1846P	No	10
Naef (29)	1998	USA	Antenatal Clinic	HTN	7	NA	102±10 (MAP)	Vasoplex	No	4-28
Lo (16)	2002	New Zealand	Antenatal Clinic	Normal	101	NA	107±8/ 66±7	Omron HEM 705CP	Yes	4 (one day only)
Rey (17)	2007	Canada	Antenatal Clinic	Normal, HTN	123	Normal 31.4 HTN 32.7	127±3/ 80±2	Aneroid	No	3-7
Rey (18)	2009	Canada	Antenatal Clinic	HTN, IOH, PET	159	HTN 32.5 IOH 29.6 PET 32.2	NA	Aneroid	No	6-14
Chung (19)	2009	United Kingdom	Antenatal Clinic	HDP	21	NA	NA	Microlife Watch BP	Yes	24
BOSHI Study (13, 14, 22)	2012, 2015	Japan	University Hospital	Normal	530	31.2	Normal 108±11/ 66±9 HTN 119±13/ 74±9	Omron HEM747IC HEM7080IC	No	7

Denolle (20)	2014	France	Antenatal Clinic	Normal	45	30	115±11/ 65±7	Hestia Pharma D2	No	36
Tucker (22)	2017	United Kingdom	Antenatal Clinic	High risk for Preeclampsia	161	31.0	117±10/ 71±9	Microlife WatchBP	Yes	12
Mikami (21)	2017	Japan	Antenatal Clinic	Normal	100	35.8	114±10/ 68±6	Omron 7251G	No	14
Perry (25)	2017	United Kingdom	Antenatal Clinic	HTN	166	32.5	NA	Microlife WatchBP	Yes	4-14
Lan (23)	2017	Australia	Antenatal Clinic	HTN	37	33.4	NA	Omron HEM-7200	No	14
Kalafat (24)	2018	United Kingdom	Antenatal Clinic	HTN	147	34	134±3/ 88±3	Microlife WatchBP	Yes	NA
Vestgaard (26)	2019	Denmark	Antenatal Clinic	Normal	103	32	115±11/72 ±7	Microlife 3A Plus	Yes	18

HBPM, home blood pressure monitor; HDP, hypertensive disorders of pregnancy; BP, blood pressure; HTN, hypertension; IOH, isolated office hypertension; PET, preeclampsia; NA, not available; BOSHI, Babies and their Parents' Longitudinal Observation in Suzuki Memorial Hospital on Intrauterine Period.

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Table 2: Summary of proposed definitions for trimester-specific upper limit of normal home blood pressure

Author	Population	Method	T1 SBP (mmHg)	T1 DBP (mmHg)	T2 SBP (mmHg)	T2 DBP (mmHg)	T3 SBP (mmHg)	T3 DBP (mmHg)
Lo (16)	Normal	Mean ± 2SD	132	82	130	79	133/138*	81/88*
Rey (17)	Normal and Hypertensive	90 th percentile	139 [^]	89 [^]	137	87	138/140/143 ^{\$}	89/90/92 ^{\$}
Denolle (20)	Normal	Mean ± 2SD	118	73	117	73	121	80
Denolle (20)	Normal	95 th Percentile	116	70	113	70	118	76
Mikami (21)	Normal	Regression line from standardized major axis methods	120.8	83.5	124/127 [#]	84/86 [#]	136	89
Vestgaard (26)	Normal	Mean ± 2SD	117	74	116	73	123	78

T1, first trimester; SBP, systolic blood pressure; DBP, diastolic blood pressure; T2, second trimester; T3, third trimester; SD, standard deviation; * blood pressure measured at 27-30 weeks and 35-37 weeks gestation; ^ blood pressure measured at less than 20 weeks gestation; \$ blood pressure measured at 28-32 weeks, 33-36 weeks, and greater than 36 weeks gestation; # blood pressure measured at 12-20 weeks and 20-24 weeks gestation

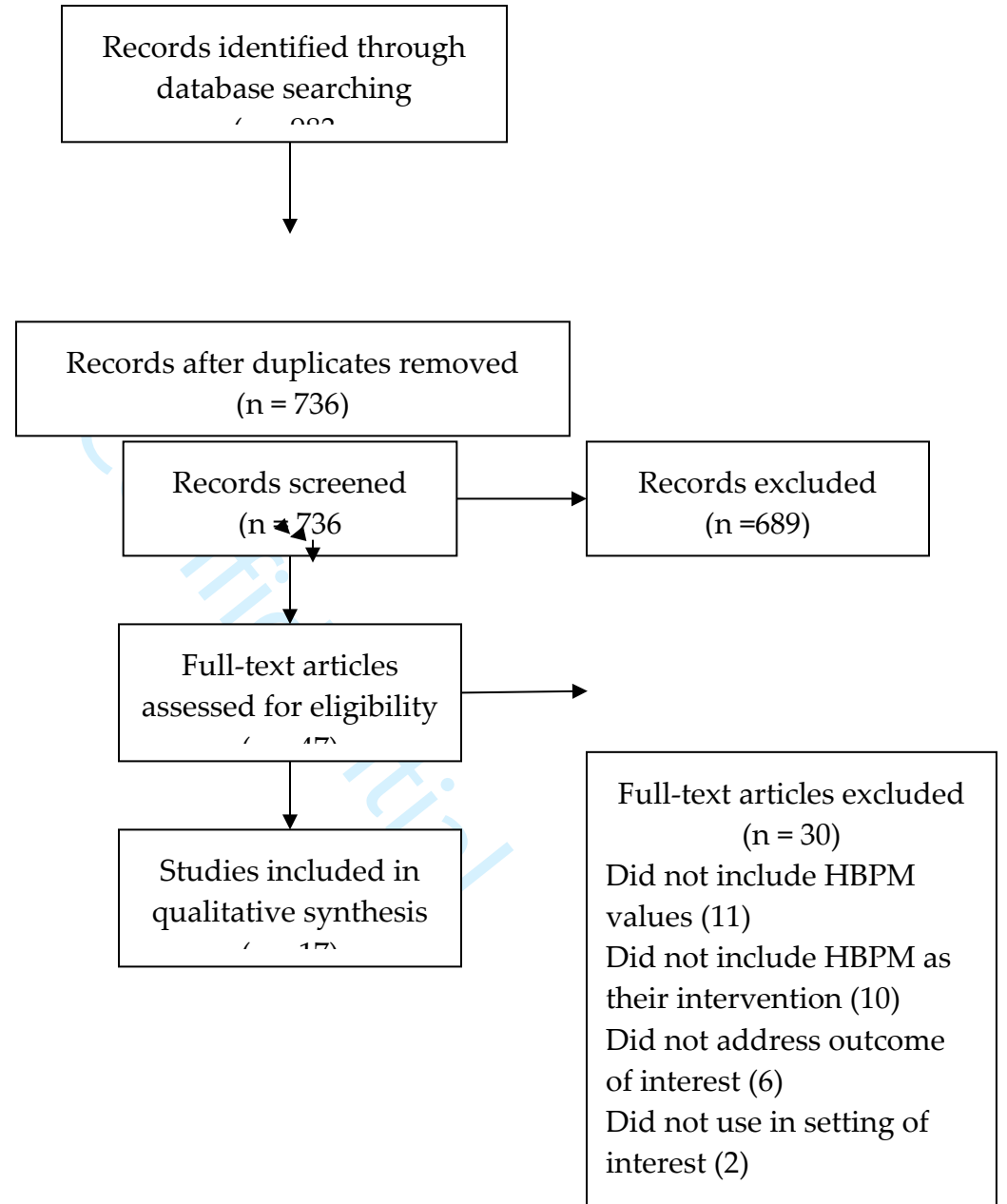
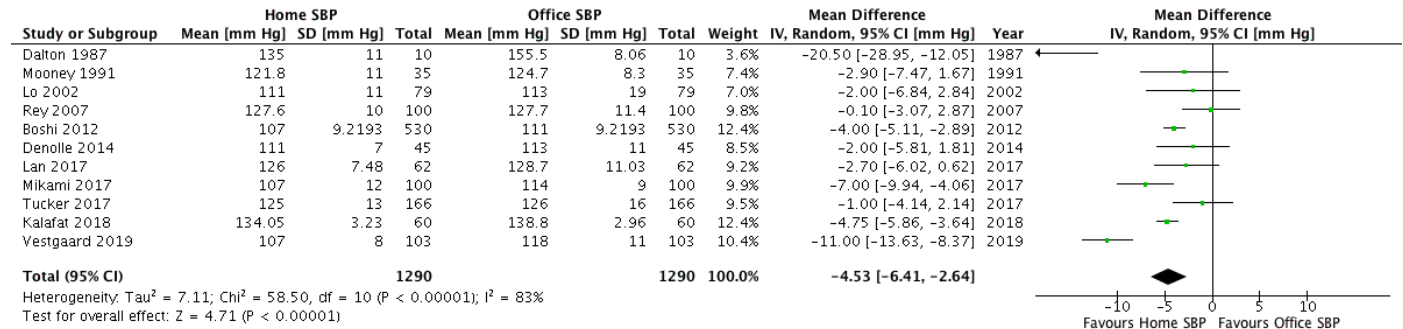


Figure 1: PRISMA flow diagram

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B.

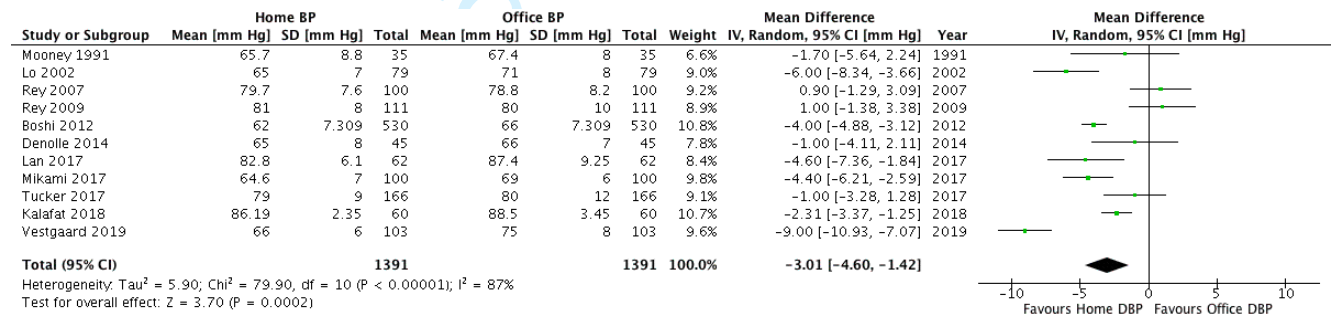
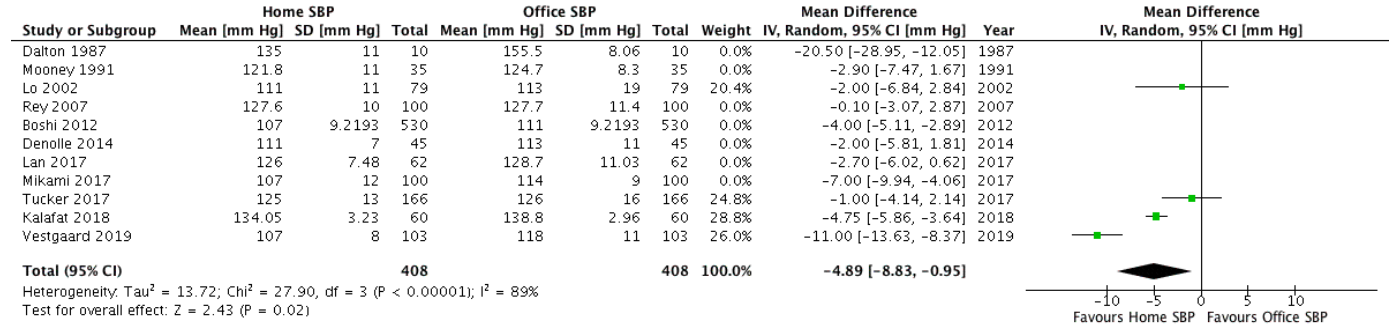


Figure 2: Forest plot of comparison: Differences in mean (A) systolic blood pressure (SBP) and (B) diastolic blood pressure (DBP) in the third trimester between home and office blood pressure measurements in pregnancy.

A.



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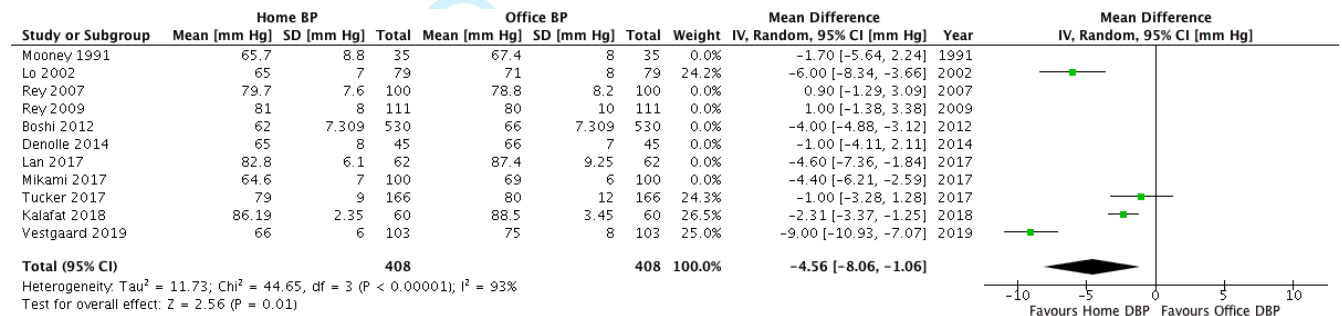


Figure 3: Forest plot of comparison: Differences in mean (A) systolic blood pressure (SBP) and (B) diastolic blood pressure (DBP) in the third trimester between home and office blood pressure measurements in pregnancy in studies using validated home blood pressure monitors.

Supplementary**EMBASE (Ovid) Search**

Performed on March 10, 2020

Database: Embase <1974 to 2020 March 10>

Search Strategy:

-
- 1 exp pregnancy/ (652065)
 - 2 blood pressure/ or blood pressure cuff/ (589054)
 - 3 (self* or home*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word] (1334076)
 - 4 exp blood pressure measurement/ (96444)
 - 5 2 or 4 (597092)
 - 6 1 and 5 (14680)
 - 7 3 and 6 (632)

EMBASE Search 632 references
1 duplicated removed

Medline (Ovid) Search

Performed on March 31, 2020

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

-
- 1 exp PREGNANCY/ (884803)
 - 2 exp Blood Pressure/ (287884)
 - 3 Blood Pressure Determination/ (27639)
 - 4 2 or 3 (299700)
 - 5 (self* or home*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1366031)
 - 6 1 and 4 and 5 (387)

MEDLINE Search 387

CENTRAL Search

Performed on March 31, 2020

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <January 2018>

Search Strategy:

-
- 1 exp PREGNANCY/ (20603)
 - 2 exp Blood Pressure/ (27108)
 - 3 Blood Pressure Determination/ (1057)
 - 4 2 or 3 (27615)
 - 5 (self* or home*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (145155)
 - 6 1 and 4 and 5 (25)

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