Performance of the Cloud DX connected HealthKit Pulsewave in home blood pressure monitoring in a pregnant population: a clinical evaluation and user experience study

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Abstract

Objective: Clinical evaluation and user experience of the Cloud DX connected HealthKit Pulsewave wrist cuff blood pressure monitor (CDXP) for home blood pressure monitoring during pregnancy (HBPM). Methods: In the first phase, an adjusted version of the European Society of Hypertension International Protocol Revision 2010 (ESH-IP 2010) was used to compare the CDXP and Omron M6 Comfort to the aneroid manometer. In the second phase, blood pressure measurement at home was compared to standard office blood pressure measurement (OBPM). Patients filled out a questionnaire regarding user experience. Results: In 34 pregnant women the blood pressure measured by the aneroid manometer did not differ from the CDXP (systolic blood pressure (SBP) difference: -0.7±6.5 mmHg (p=0.38), diastolic blood pressure (DBP) difference: 0.4±5.7 mmHg (p=0.55)), while the aneroid manometer measured SBP slightly higher (1.5±5.8 mmHg (p=0.04)) and DBP slightly lower (-2.8±5.8 mmHg (p<0.01)) as compared to the Omron M6 Comfort. In 32 patients the SBP of the office hospital measurement was significantly higher, while DBP was comparable. The mean user experience score for the CDXP was 85%, corresponding with an 'excellent' evaluation. Of all patients, 97% reported they liked the idea of home monitoring and would like to use it in the future. Conclusion: The CDXP is as reliable as standard office blood pressure monitors during pregnancy and gives a better representation of the blood pressure than standard hospital measurement. Pregnant women are positive and confident about HBPM and find the CDXP easy to use.

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The mean user experience score for the CDXP was 85%, corresponding with an 'excellent' evaluation. Of all patients, 97% reported they liked the idea of home monitoring and would like to use it in the future.

Conclusion: The CDXP is as reliable as standard office blood pressure monitors during pregnancy and gives a better representation of the blood pressure than standard hospital measurement. Pregnant women are positive and confident about HBPM and find the CDXP easy to use.

Tweetable abstract

The CDXP is reliable and gives a better representation of the blood pressure than standard hospital measurement during pregnancy

Key words: blood pressure, pregnancy, telemedicine, home monitoring, device

Introduction

Gestational hypertensive disease (GHD) complicates 10% of all pregnancies.[1-4] and is a major risk factor for maternal and fetal morbidity and mortality.[5,6]. Therefore, repeated blood pressure measurements are necessary for early diagnosis of GHD and detection of progression.[3,7-10]For that reason, blood pressure monitoring during pregnancy is of high importance.

Currently the gold standard for blood pressure monitoring during pregnancy is aneroid office measurement.[11] However, a substantial part of the pregnant population suffering from 'white coat hypertension' is unnecessarily closely monitored and treated for hypertension.[12,14](11) The use of home blood pressure measurement (HBPM) may overcome this disadvantage.

Current guidelines recommend home blood pressure monitoring (HBPM) as a more suitable alternative.[13,15] It is already known that pregnant patients are willing to undertake repeated self-measurements[16]. Further-

more, HBPM can be cost-effective when leading to less outpatient visits[17] and is a better predictor for cardiovascular morbidity and mortality than office blood pressure measurement (OBPM) in non-pregnant subjects.[14] However, little is known about HBPM during pregnancy.[16]A clinical evaluation of an easy-to-use device during pregnancy is still lacking.[18-20]

The Cloud DX connected HealthKit Pulsewave wrist cuff blood pressure monitor (CDXP) is a commercially available monitor that has yet not been evaluated in a pregnant population, but could be exactly the kind of modern device that has potential for the use in HBPM during pregnancy.

The aim of this study was to evaluate the CDXP in a clinical setting, to assess its performance at home and to assess user experience.

Materials and methods

Tested device

The CDXP is an oscillometric automatic digital wrist cuff blood pressure monitor and is connected to a tablet by Bluetooth connection (Table 1). A scale, a saturation measurement device and a thermometer can also be linked to the tablet (these functions will not be tested in this study). The tablet shows the patient a detailed protocol, giving instructions of how to apply the wrist cuff and how to be positioned. After 60 seconds the blood pressure and heart rate (HR) are shown. It is possible to link the connected device to the to the patients' medical records in the hospital.

Standard office device

The Omron M6 Comfort is an oscillometric automatic digital upper arm blood pressure monitor suitable for home and clinical blood pressure measurements, which is frequently used but also not validated in pregnancy (Table 1). However, comparable other series of Omron Healthcare have been validated in pregnancy.[21] It is not possible to link the connected device to the to the patients' medical records. In our hospital this device was used at the time of phase 1 of this study as a standard for measuring blood pressure at the outpatient clinic.

The Welch Allyn 53000P is an oscillometric automatic digital upper arm blood pressure monitor suitable for clinical blood pressure measurements, which has been validated for the use in pregnancy[22] (Table 1). To deal with the influence of physician induced white coat hypertension, we changed the logistic at our outpatient clinic during phase 2 of this study, where standard office blood pressure measurement was performed in a quiet room by an obstetric nurse. For this, Welch Allyn 5300P was used.

Gold standard device

Due to the mercury's toxicity the mercury sphygmomanometer is no longer used in the Radboudumc. In line with literature we used the aneroid manometer as the gold standard. One trained observer performed the blood pressure measurements. The observer had adequate hearing and sight and the aneroid manometers was calibrated accurately.

Familiarization

Before the start of the study testing measurements were conducted to familiarize the observer with the three different devices.

Study design

This study consisted of two phases. In the first phase we evaluated the performance of the CDXP in comparison with the Omron M6 Comfort in a clinical setting. In the second phase we compared the blood pressure measured by the CDXP at home with the blood pressure measured inside the hospital and assessed the user experience of the CDXP for HBPM. This study was approved by the Radboudumc Medical Ethics Committee (filenumber: 2016-2699, 14-06-2017).

Recruitment

Pregnant women visiting the outpatient clinic of the Radboudumc in Nijmegen, the Netherlands, were eligible for inclusion. For both parts of this study patients were separately included. All women lived in Nijmegen and surroundings, were over the age of eighteen, provided written informed consent, had all of their regular pregnancy check-ups to the Radboudumc and had a blood pressure of 80-190 mmHg systolic and 30-140 mmHg diastolic. Women with diagnosed arrhythmia, edema in the arms or unable to give their written informed consent in Dutch were excluded.

Phase 1

For this phase we included women with a gestational age over 30 weeks, as this period of pregnancy is accompanied by the largest variability in blood pressure and most hypertensive disorders occur in this period. We aimed for an inclusion of at least 30 women in line with the ESH-IP 2010 protocol.

Phase 2

In this phase we included women of all gestation ages to evaluate home versus office blood pressure measurements from the first to third trimester. We aimed for an inclusion of at least 30 women as well.

Procedure

Phase 1

In order to evaluate the clinical performance of the CDXP we used an adjusted version of the ESH-IP 2010 that is suitable for non-pregnant validation studies to make it clinically more applicable for use in a pregnant population. First, all measurements were conducted by the same observer, as resembles the outpatient clinical situation. Second, a total of two measurements per tested device were performed for the same reason. Third, the blood pressure ranges from the ESH-IP 2010 were lowered to the physiological blood pressure ranges during pregnancy. Fourth, we used an aneroid blood pressure device as a gold standard as a mercury blood pressure device is not allowed in our hospital.

After their regular check-up in the outpatient clinic, women were asked for participation in this study. After informed consent, women were seated in a comfortable chair in a room with a comfortable temperature, refrained from talking and moving around for a period of 10 minutes. A total of six blood pressure measurements was conducted in two rounds on each participant. Each round consisted of two measurements with the CDXP, the Omron M6 Comfort (randomization was performed to determine the consecution) and the aneroid manometer. All measurements were performed on the non-dominant arm because participants will use their dominant hand to fasten the wrist cuff at home. Maternal age, height, weight, gestational age, circumference of upper arm and wrist of the non-dominant side and the use of antihypertensive medication were documented, as well as any peculiarities (arrhythmia, error of the measuring device, poor sound quality or others).

Phase 2

In the second phase we focused on the performance of the CDXP for HBPM. Measurements were performed under three conditions: standard office measurement, office self-measurement and home self-measurement. Prior to their appointment a doctor's assistant carried out the standard office blood pressure measurement with the Welch Allyn 5300P. After their appointment, patients were asked to conduct two office-self-measurements using the CDXP, receiving elaborate instructions. After the office self-measurement the CDXP was given home along with written instructions and women were asked to measure their blood pressure at home after ten minutes of rest at four timepoints during the day: around 8:00 am, 12:00 pm, 18:00 pm and 22:00 pm. At each timepoint of measurements patients were asked to carry out two blood pressure measurements with a one-minute interval. The following patients' characteristics were collected: BMI before and during pregnancy, age, amenorrhea duration, parity, the diagnosis of pre-existing or gestational hypertension, upper mid arm and wrist circumference.

After the blood pressure measurements patients' experience was evaluated by questionnaire, containing fifteen questions (Table 3). Ten questions, regarded the user's experience, were based on the system usability scaled

(SUS)[23]. Five other general questions were included as well. All questions were scored using the five-point Likert-scale, ranging from 'strongly disagree' to 'strongly agree'.

Statistical analysis

The obtained data were analyzed using SPSS Statistics version 22. All blood pressure values are presented as mean±SD. First, using a paired t-test, the SBP and DBP measured with the CDXP and the Omron M6 Comfort were compared to the aneroid manometer. Second, a linear regression analysis was used to determine whether body mass index, parity, gestational age, upper arm circumference and wrist circumference had any influence on the blood pressure differences between the devices. Third, Bland-Altman plots were created to visualize the performance of the devices. Following the ESH-IP 2010 protocol, the found blood pressure differences were divided into four groups: difference of [?]5 mmHg, [?]10 mmHg, [?]15 mmHg and >15 mmHg. Fourth, the systolic and diastolic blood pressure of the office measurements and the home self-measurements of the CDXP were compared by using a paired t-test. When applicable, Bonferroni correction was applied for multiple comparisons. The SUS score was calculated with the first ten questions of the questionnaire following the standard ranging from 0 till 100%[22]. The mean score from the other 5 questions was calculated, ranging from 1 till 5.

To achieve a power of 95% with an α significance level of 0.05 a sample size of 22 was estimated, with the variation of difference in blood pressure being 5 mmHg and the chosen relevant difference being 5 mmHg. All analyses were carried out using SPSS version 22. P-values less than 0.05 were considered statistically significant.

Results

Phase 1: Performance evaluation of the CDXP and Omron M6 Comfort

Of the approached 68 women 34 were willing to participate and met the inclusion criteria as described above. Participant details of this phase are shown in Table 3. A total of 33 complete measurements with the CDXP, Omron M6 Comfort and the aneroid manometer were conducted. 1 Participant was excluded in the comparison of the CDXP due to the inability to refrain from moving the arm.

The mean aneroid recruitment SBP was 113 mmHg (93-147 mmHg), the mean DPB was 73 mmHg (59-99 mmHg). We did not detect any difference in SBP and DBP between the aneroid meter and CDXP: -0.7±6.5 mmHg (p=0.38) and 0.4±5.7 mmHg (p=0.55) for SBP and DBP respectively. The aneroid manometer measured SBP mmHg significantly higher (1.5±5.8 (p=0.04)) and DBP lower (-2.8±5.8 mmHg (p<0.01)) as compared to the Omron M6 Comfort. Using an univariate regression analysis we did not find a difference between measurements in round 1 and 2 and we could not explain the differences in blood pressure measurements between the Omron M6 Comfort and the aneroid manometer by body mass index, gestational age, upper arm or wrist circumference.

Figure 1 and 2 illustrate Bland-Altman plots of both the CDXP and Omron M6 Comfort and shows that there is no indication of a systematic relation between the blood pressure ranges and the performance of the two devices.

Phase 2: Home CDXP versus office blood pressure measurement

Of the 64 approached women 32 were willing to participate and met the inclusion criteria as described above. 3 Women accidently measured their home measurement on a different day as their hospital measurement and were excluded from statistical analyses. Participant details of this phase are shown in Table 3.

The mean blood pressure values and the mean differences between measurements are listed in Table 4. In 7 patients the home blood pressure measurements were not complete due to technical problems (n=3), simply forgetting (n=3) and going into labor during the measurements (n=1). Their available partial data were incorporated in the analysis. Comparison showed that for both CDXP self-measurements the SBP, but not the DBP, was significantly lower than the standard office measurement. The second measurement of the office self-measurement was slightly significantly lower than the first measurement. This was not observed in home

self-measurement. The found significant differences in office SBP and home SBP was not correlated with age, amenorrhea duration, BMI before and during pregnancy, parity, wrist and upper mid arm circumference, pulse rate and the range of blood pressure (data not shown).

Evaluation of the home self-measurements with the CDXP during the day showed that there were small differences between the first and second home self-measurement at the different time points in both SBP (maximum of 2.3±4.6 mmHg) and DBP (maximum of 2.1±3.1 mmHg). Figure 3 shows the mean standard office measurement and mean first home self-measurements of SBP and DBP over the different time points. The standard office measurement of SBP was significantly higher as compared to all time points of the home self-measurement: morning 6.7±10.5 mmHg, noon 7.6±9.7 mmHg, afternoon 7.6±10.7 mmHg, night 7.2±11.9 mmHg. We did not detect any difference in DBP between the standard office measurement and the home self-measurement time points.

Table 5 shows the mean scores to the patients' experience questionnaire. Two patients did not fill out the questionnaire and two patients left one question blank and were therefore excluded from analysis. The mean SUS-score was 85%, corresponding with an excellent score. Most women indicated that they managed to follow all the instructions and that they trusted their measured blood pressure. The vast majority thought that home monitoring of the blood pressure is a good idea and a good option for replacement of the standard office measurement. Most women liked the idea of having less hospital visits due to home monitoring, while only 3% disagreed. Women reported that they rather not miss listening to the fetal heart. Patients also reported that they liked the idea of home monitoring of the blood pressure even more if the course of pregnancy led to extra hospital visits for blood pressure measurement only.

Discussion

Main findings

This study provides a clinical evaluation of the CDXP for the use in self-measured HBPM and user experience during pregnancy. We found that the CDXP measures blood pressure as reliable as the Omron M6 Comfort and that the self-measured home SBP was significantly lower and more representative than the standard office SBP. Pregnant women are positive about HBPM and find the CDXP easy to use. The CDXP could be a reliable and attractive instrument for HBPM during pregnancy.

Interpretation

We observed that the CDXP measured blood pressure as reliable as the Omron M6 Comfort, which has been validated for the use during pregnancy. We did not find any association between body mass index, gestational age, upper arm or wrist circumference, or height of blood pressure and the difference between the CDXP and gold standard. Literature reports similar ranges of deviation of upper-arm devices[22, 24]. Although blood pressure measurement using an upper-arm device is thought to be superior, we did not detect clinically relevant differences[25]. The above implies that the CDXP seems to qualify for the use for home blood pressure monitoring.

Our study showed that OBPM under our regular check-up circumstances (several minutes after entering the consult room with the physician present) is significantly higher than the self-measured blood pressure under more standardized conditions: 5 minutes of rest, sitting in a chair against the backrest, non-crossed legs placed on the ground and no physician present. This is in line with literature on pregnant and non-pregnant individuals [28, 30, 31]. 'White coat hypertension' may lead to overdiagnosis of hypertension when blood pressure is not measured under ideal circumstances [29]. Self-measuring blood pressure with the CDXP helps to meet these criteria.

The blood pressure used for monitoring and early detection of pregnancy-related disorders needs to represent the blood pressure during the day. We observed that HBPM using the CDXP during pregnancy is completely stable during the day. Self-measured home blood pressure at a single time point gives a good reflection of the blood pressure during the day. Several studies show comparable differences between OBPM and HBPM in both pregnant and non-pregnant subjects [26-28, 32]. Our data is also in line with Hermida et al., that

demonstrated that blood pressure is very stable during daytime and drops during the night [4]. This implies that HBPM gives a better reflection of the actual blood pressure during pregnancy than OBPM.

The success of changing OBPM to self-measured HBPM also depends on user experience and satisfaction. Our study is in line with previous literature, where 98% of women with gestational hypertensive disease liked involvement in their blood pressure management and declared to have more confidence in HBPM to represent their usual blood pressure[16, 33, 34]. Our study showed that pregnant women liked the idea of self-measuring their blood pressure, they found the CDXP easy to use and they felt confident about the reliability of their self-measured blood pressure.

Strengths and Limitations

One major strength of this study is that the findings can be directly translated into everyday practice. Due to the adjustments we made to the original ESH-IP 2010, this study provides valuable information concerning the implications of the use of such a device in clinical practice. Along with research this study also has some potential methodological imperfections that need to be addressed. First, we did not perform a validation study following the strict criteria the ESH-IP 2010 protocol. Critics might say that the CDXP needs a validation before it can be used in daily practice. However, we showed that the margins of difference from the gold standard are comparable to the validated Omron M6 Comfort. Therefore, we think our data show that the CDXP is just as reliable. Second, it was necessary to adjust the blood pressure ranges of the ESH-IP 2010 to make it directly applicable on a pregnant population, as normal blood pressure ranges strongly differ from a non-pregnant population[9]. Third, we used one non-blinded observant taking all the measurements instead of two blinded observants as proposed by the ESH-IP 2010. However, as the observant measured the aneroid blood pressure before the device measurements we do not think this influenced our results. Fourth, in phase 1 and 2 we used different reference devices (Omron M6 Comfort and Welch Allyn 5300P) to compare to the CDXP. Although both reference devices have been validated in pregnancy, this theoretically might have induced small differences between the two phases. However, we do not think this to be clinically relevant. We think the CDXP can be used for HBPM during pregnancy.

Conclusion

The CDXP is a reliable blood pressure device to use in pregnancy for home monitoring. Pregnant women are confident and positive about the idea of home blood pressure measurement and find the CDXP easy to use. Using the CDXP for home blood pressure monitoring gives a better representation of the patient's blood pressure than the standard hospital measurement. The CDXP can therefore be a reliable device for the use in home blood pressure monitoring during pregnancy.

Contribution to authorship

Hofstede, A: responsible for literature search, planning, combining phase 1 and 2, writing final draft of article, publication process

Lomme, M.: responsible for carrying out and analyzing phase 1 of this study, writing first draft of phase 1

Gosselink, S.: responsible for carrying out and analyzing phase 2 of this study, writing first draft of phase 2

Van Drongelen, J.: responsible and guiding gynecologist, writing first and final draft of article

Authors' Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Tables and Figures Caption List

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Table 2 : Questionnaire

Table 3 : Subject details phase 1 and phase 2

Table 4 : Mean blood pressure and mean blood pressure differences between the standard office measurement with the Welch Allyn 5300P, and the first office self-measurement and the first home self-measurement with the Cloud DX Connected HealthKit Pulsewave.

Table 5 : Results questionnaire

Figure 1: Bland-Altman plots of systolic blood pressure (A, 66 dots) and diastolic blood pressure (B, 66 dots) measured by the Cloud DX Pulsewave Wrist Blood Pressure Monitor in comparison to the aneroid manometer.

Figure 2: Bland-Altman plots of systolic blood pressure (A, 68 dots) and diastolic blood pressure (B, 68 dots) measured by the Omron M6 Comfort in comparison to the aneroid manometer.

Figure 3 : Systolic blood pressure (A) and diastolic blood pressure (B) evaluated by the standard office measurement and four different time points of home self-measurements first measurement with the Cloud DX Pulsewave Wrist Blood Pressure Monitor (morning, noon, evening, night) (n=29).

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