SAFE@HOME: Digital health platform facilitating a new care path for women at increased risk of preeclampsia – A case-control study

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ABSTRACT

Objective: In women at risk of developing preeclampsia, we evaluated the use of a digital health platform for telemonitoring blood pressure and symptoms combined with a minimal antenatal visit schedule.

Study design: A case-control study for women with chronic hypertension, history of preeclampsia, or maternal cardiac or kidney disease. A care path was designed with reduced visits enhanced with a digital platform (SAFE@HOME) for daily blood pressure and symptom monitoring starting from 16 weeks of gestation. Home-measurements were monitored in-hospital by obstetric professionals, taking actions upon alarming results. This prospective SAFE@HOME group was compared to a retrospective control group managed without self-monitoring.

Main outcome measures: Primary: healthcare consumption (number of antenatal visits, ultrasounds, admissions and diagnostics), user experiences of the platform. Secondary: maternal and perinatal outcomes.

Results: Baseline characteristics of the SAFE@HOME (n = 103) and control group (n = 133) were comparable. In the SAFE@HOME group, antenatal visits (mean 13.7 vs 16.0, p < 0.001) and ultrasounds (6.3 vs 7.4, p = 0.005) were lower compared to the control group. Admissions for hypertension or suspected preeclampsia were significantly fewer in the SAFE@HOME group (2.9% versus 13.5%, p = 0.004). Telemonitoring participants were highly satisfied using the platform. No differences were observed for maternal and perinatal outcomes.

Conclusions: Our care path including blood pressure telemonitoring for women at risk of preeclampsia allows fewer antenatal visits, ultrasounds and hypertension-related admissions. We observed no differences in perinatal outcomes. These results suggest that telemonitoring of blood pressure is feasible in a high-risk pregnant population and has the potential to profoundly change antenatal care.

1. Introduction

Hypertension in pregnancy is increasingly common, and an important cause of maternal and neonatal morbidity and mortality, at short as well as long term [1,2]. Frequent monitoring of blood pressure (BP), fetal growth, blood and urine during pregnancy is recommended to early identify and monitor hypertensive disease [3]. Interfering with daily life, (un)planned visits and hospitalization pose a substantial burden to patients and care resources [4].

International guidelines from 2013 onwards recommend self-measurements for patients with (gestational) hypertension [5–7]. Recent research has shown that pregnant women are willing to undertake repeated self-measurements for involvement of blood pressure management [8–10]. As such, the adoption of digital health has been suggested to achieve higher-value antenatal care [11].

We developed a digital telemonitoring platform enabling home blood pressure measurements and preeclampsia symptom reporting [12]. This redesign of antenatal care, with a predefined minimal visit schedule and telemonitoring, is anticipated to enhance digital interaction and women’s autonomy while maintaining safety of antenatal care. Furthermore, telemonitoring might allow less frequent antenatal visits. It could potentially also lead to more visits as a result of an overload of
data or questions in contrast. The precise role of digital exchange of home measurements in pregnancies at increased risk has yet to be established.

We evaluated our digital health platform in antenatal care for patients at increased risk of developing preeclampsia, together with a newly developed reduced antenatal visit schedule, from 16 weeks gestational age onwards.

2. Methods

2.1. Study population and design

This case-control study was conducted in two perinatal centres in urban areas in the Netherlands: one university hospital (2500 deliveries annually, both secondary and tertiary care) and one general teaching hospital (3000 deliveries annually). The study population consisted of pregnant women with a singleton pregnancy and one (or more) of the following risk factors for preeclampsia: chronic hypertension, preeclampsia in a prior pregnancy, maternal cardiac disease, or maternal kidney disease. A prospective group of women, managed with use of the digital platform, was compared with a retrospective group with identical risk factors at start of pregnancy, but managed with conventional care. This study was submitted to the Medical Ethics Committee of the University Medical Center in Utrecht (17/424). The committee judged that the Dutch Medical Research Involving Human Subjects Act (WMO) did not apply to this study.

The SAFE@HOME group consisted of women, who presented with one of the fore-mentioned risk factors between October 2017 and December 2018. Eligible candidates for the prospective study were >18 years of age, had access to a smartphone or tablet with Internet connection and could understand Dutch or English language. Kidney transplant patients and arm circumference >42 cm (as prescribed by the instructions of the monitor) were considered an exclusion criterion.

The control group consisted of retrospectively selected women with one of the aforementioned four risk factors at start of pregnancy. After database search for these risk factors amongst all deliveries between 1 and 1-2015 and 31-12-2016, patients were included in this control group only if they received antenatal care from intake to delivery in the same centre. Exclusion criteria were maternal age <18 years and kidney transplant. Antenatal care in the control group was based on the Dutch guideline on hypertensive disorders of pregnancy, without use of home blood pressure measurements [13]. Follow-up visits were planned once per two weeks, with increased frequency if indicated by their care provider, depending on the patient’s condition, BP or medication use. Antihypertensive medication was generally prescribed in case of blood pressure >160/110 mmHg. Hospitalization was recommended in case of preeclampsia, or fetal growth restriction with indication for daily cardiotocography (pulsatility index of the umbilical artery >95th centile).

2.2. Intervention

The digital health platform consisted of the Luscii platform (by Focuscure, in collaboration with UMC Utrecht) and the iHealth Track automated blood pressure monitor, validated for use in pregnancy [14].

Development of the platform was described before and its use was found feasible in our hospital setting in a low risk pregnant population [12]. This study showed good participant compliance and high accuracy of the alarm system [12]. Subsequently, telemonitoring with the platform was offered to patients at risk of preeclampsia from October 2017 onwards. As part of this novel strategy, a uniform care path was predefined (Fig. 1). We organized 4 multidisciplinary meetings with obstetricians, internists, cardiologists and nephrologists, nurses and patients for the development of the schedule. Considering the home-measurements and symptom scores, they discussed the desired structure of care, outcome measures of interest and the objective of each planned clinic and ultrasound visit.

Before start of the study, a local telemonitoring team was set up. Nurses and midwives of these teams were trained in a 1-h course to 1) register and instruct new participants to use the monitor and platform and 2) perform daily monitoring of alerts and subsequent actions. Obstetricians (in training) were trained how to access the home measurements and to plan future appointments using the predefined schedule.

Women who gave written informed consent were provided access to the secured platform from 16 weeks gestational age onwards. They were trained to obtain correct measurements with the iHealth Track. From study enrolment to delivery date, they were asked to submit a single blood pressure on weekdays before 10.00AM. In-app or email reminders were sent automatically at 7.00AM. The blood pressure measurement was transferred to the app with Bluetooth, and the pregnant woman could forward it to the platform after manual check. If blood pressure was raised, participants answered an in-app symptom checklist, containing 10 yes/no questions for symptoms that occur in the development of preeclampsia as well as general pregnancy symptoms (Table 1). Uploaded values were visible for both the patient and the healthcare provider, on a monitoring dashboard in the electronic health record.

Values exceeding the set threshold values led to alerts on the monitoring dashboard, reviewed by a member of the telemonitoring team every weekday at 10.30 AM. Alerts were set for a systolic value of >140 mmHg or diastolic >90 mmHg and/or an increase of 20 mmHg compared to the previous measurement. These thresholds were chosen as they indicate new-onset of gestational hypertension following international consensus, but can be altered in the dashboard to provide individual care [15–17]. For the symptom checklist, the platform alarmed if ≥1 symptoms were present. Alerts were reviewed with a protocol of flowcharts taking into account several combinations of hypertension and symptoms (Supplementary Fig. 1). If needed, the telemonitoring team would consult the obstetrician and subsequently contact the participant to advice one of the following: 1) expectant management or 2) same-day clinical assessment of blood pressure and symptoms and 3) if necessary with blood/urine analysis, 4) adjustment of antihypertensive therapy, 5) admission to the antenatal ward, and 6) induction of labour. To ensure patient safety, all alerts in the dashboard had to be switched off manually after processing the protocolled steps.

In both study groups therapeutic interventions including induction of labour or caesarean section were started according to local protocol based on the Dutch national guideline [13].

2.3. Outcomes and data collection

Primary outcomes were healthcare consumption and user experiences of the digital telemonitoring platform. Secondary outcomes were maternal and neonatal perinatal outcomes.

For healthcare consumption, the number of antenatal visits, ultrasounds for fetal assessment, blood and urinary analysis, medication use and admissions were extracted from participants’ hospital system.

For user experiences, SAFE@HOME participants were invited to answer an online survey at 36 weeks of gestation with 10 statements regarding their experiences with the platform on a 5-point Likert scale. Derived from the Luscii webportal, the start, duration and frequency blood pressure and symptom monitoring, as well as number of alerts and raised readings were recorded.

For maternal and perinatal outcome, pregnancy and delivery data were recorded and used to compare both groups. Risk factors for preeclampsia in each group and other maternal characteristics were collected at baseline from hospital records. Chronic hypertension, gestational hypertension, preeclampsia and eclampsia were defined according to ISSHP criteria [15].
2.4. Statistical analyses

Given the exploratory nature of this study, no formal sample size calculation was performed. Continuous outcome variables were represented as means with standard deviations or, if skewed, medians with interquartile ranges (IQR), and were compared by the Student’s \( t \)-test or Mann-Whitney-\( U \) test. Categorical outcome variables were compared between groups by the chi-square or Fisher’s exact test. \( P \)-values below 0.05 were considered as statistically significant. Statistical analysis was performed with IBM SPSS version 25.

3. Results

For the SAFE@HOME group, 111 women were found eligible and invited to participate, of which 109 consented (Fig. 2). During the study period, 2 participants experienced pregnancy loss < 21 weeks of gestation, and 2 were lost to follow-up. Only 2 women (2%) were excluded from the SAFE@HOME strategy and returned to standard care because they were non-compliant to study instructions. For the final analysis, 103 participants were included in the SAFE@HOME group.

In the control group, 133 eligible women were included. Fig. 3 shows the selection of these 133 participants from retrospective database search.

Baseline characteristics are shown in Table 2. Maternal age, BMI, ethnicity, education level and parity were similar between groups, as were history of hypertensive disorders of pregnancy (HDP) and intake blood pressure. The distribution of the four risk factors for pre-eclampsia, as reason for study inclusion, was comparable for pre-eclampsia in prior pregnancy, chronic hypertension and maternal cardiac disease. However, more women with kidney disease were included in the SAFE@HOME group (16.5% vs 4.5%, \( p = 0.002 \)), as one of the study centres became a referral centre for kidney disease in pregnancy during the intervention period.

3.1. Healthcare consumption

Table 3 demonstrates healthcare consumption during pregnancy. The number of antenatal visits from the first visit to delivery was significantly lower in the SAFE@HOME group as compared to the control group (mean 13.7 [4.1] vs 16.0 [4.0], \( p < 0.001 \)). The total number of ultrasound assessments was also significantly lower in the SAFE@HOME group (mean 6.3 [2.7] vs 7.4 [2.9], \( p = 0.005 \)). These significant reductions were primarily observed between 34 weeks of gestation and delivery, which corresponds to the proposed visit schedule (Fig. 1 and Table 4).

In the SAFE@HOME group, observational admissions for hypertension or diagnosis/exclusion of suspected preeclampsia were significantly lower compared to the control group (2.9% vs 13.5% of...
participants, \( p = 0.004 \), Table 3). Overall, no significant difference was found in the number of patients who needed an antenatal admission for any other obstetric indication (i.e. fetal monitoring, antepartum haemorrhage or intravenous treatment for severe hypertension or pre-eclampsia): 31.1% in SAFE@HOME vs 39.1% in control group, \( p = 0.20 \). The mean number of blood tests for evaluation of hypertension/pre-eclampsia did not differ between groups.

### 3.2. User experiences and data on home measurements

The online survey on SAFE@HOME experiences was answered by 51 (49%) participants. Few had difficulties with using the system (4%, 2/51) and instructions regarding the use of the BP monitor and app were clear to almost all (96%, 49/51) (Supplementary Fig. 2). Daily measurement took \( \leq 5 \) min for 81% (mean 4.6 min), and 98% (50/51) could easily perform their routine tasks while using the platform. The vast majority was satisfied with the use of the app and platform (92%, 47/51) and especially parous participants would recommend it to other women (96.9% of multiparous vs. 73.7% of nulliparous women).

Telemonitoring participants started their home measurements on average at 17.9 weeks of gestation (SD 3.9) and continued this for 20.2 weeks (SD 4.0) until delivery (Table 2). During pregnancy, the median number of uploaded blood pressure measurements per participant was 90.0 in total (IQR 68.0–107.0, range 18–201) or 4.5 per week of telemonitoring (IQR 3.6–5.0, range 0.9–12). The median compliance rate for all scheduled blood pressure measurements was 91.2% (IQR 70–100, range 34–100).

### Table 3
Results of healthcare consumption.

|                                  | SAFE@HOME | Control | \( \text{p-value} \) |
|----------------------------------|-----------|---------|-------------------|
| **Total number of visits**       | mean (SD) |         |               |
| GA 0–26 weeks                    | 13.7 (4.0) | 16.0 (4.1) | 0.001 |
| GA 26–34 weeks                   | 5.9 (2.5) | 6.2 (2.4) | 0.23 |
| GA 34– delivery                  | 4.1 (2.0) | 4.5 (2.0) | 0.16 |
| **Total number of ultrasound assessments** | mean (SD) |         |               |
| GA 0–26 weeks                    | 6.3 (2.7) | 7.4 (2.9) | 0.005 |
| GA 26–34 weeks                   | 2.8 (1.5) | 3.5 (1.5) | 0.001 |
| GA 34– delivery                  | 2.7 (1.6) | 2.6 (1.7) | 0.58 |
| **≥1 antenatal admissions (for any obstetric indication)** | n (%) |         |               |
| Duration (days)                  | 32 (31.1) | 52 (39.1) | 0.20 |
| **≥1 antenatal admissions for observation of hypertension or suspected preeclampsia** | n (%) |         |               |
| Duration (days)                  | 3 (2.9) | 18 (13.5) | 0.004 |
| **Number of blood tests for hypertension evaluation** | mean (SD) |         |               |
|                                  | 2.9 (3.7) | 2.5 (3.6) | 0.38 |

(GA, gestational age; PE, preeclampsia.)
3.3. Perinatal outcome

Table 4 shows the pregnancy outcomes in both groups. At delivery, diagnoses of gestational hypertension, preeclampsia, chronic hypertension without superimposed preeclampsia or normotensive pregnancy were similar between groups. Approximately 20% of all participants developed preeclampsia, and fetal growth restriction (estimated fetal weight <10th centile) occurred in ±10% of all pregnancies (Table 4). Labour induction was more frequent in the SAFE@HOME group (56.3 vs 38.3%, p = 0.006). However, hypertension as the main indication for induction was not significantly different between groups (56.9 vs 54.9% of inductions, p = 0.99). Planned induction for patients with cardiac disease was more frequent, although not significant, in the SAFE@HOME group (16.5 vs 9.0%, p = 0.08). No other differences were found regarding mode of delivery.

One antepartum fetal death, not related to telemonitoring, occurred in the SAFE@HOME group, in a woman included because of a history of preeclampsia. There were no maternal complications. No other serious adverse events were observed in both groups.

In general, no differences were detected in use of (iv) anti-hypertensive drugs, magnesium sulphate or glucocorticoids for fetal lung maturation (Table 4). Results were also similar for gestational age at

| Table 4 | Pregnancy outcomes. |
|---------|---------------------|
|          | SAFE@HOME n = 103 | Control n = 133 | p-value |
| Final maternal diagnosis of HDP in current pregnancy | n (%) | n (%) |  |
| Gestational hypertension | 9 (8.7) | 4 (3.0) | 0.06 |
| Preeclampsia | 22 (21.4) | 27 (20.3) | 0.84 |
| HELLP syndrome | 1 (1.0) | 0 (0.00) | 0.44 |
| Chronic hypertension without superimposed PE | 23 (22.3) | 26 (19.5) | 0.60 |
| No HDP (normotensive) | 48 (46.6) | 76 (57.1) | 0.11 |
| Suspected fetal growth restriction | n (%) | n (%) |  |
| Glucocorticoid administration | 12 (11.7) | 13 (9.8) | 0.64 |
| MgSO4 administration | 15 (14.6) | 10 (7.5) | 0.08 |
| Use of anti-hypertensive drugs <20 w GA | n (%) | n (%) |  |
| Use of antihypertensive drugs >20 w GA | n (%) | n (%) |  |
| Iv antihypertensive drugs ante-partum | n (%) | n (%) |  |
| Iv antihypertensive drugs post-partum | n (%) | n (%) |  |
| Mode of delivery | n (%) | n (%) |  |
| Induction of labour because of hypertension | n (%) | n (%) |  |
| Primary caesarean section because of hypertension | n (%) | n (%) |  |
| Vaginal delivery | n (%) | n (%) |  |
| Instrumental delivery | n (%) | n (%) |  |
| Secondary caesarean section | n (%) | n (%) |  |
| Fetal/neonatal outcome | n (%) | n (%) |  |
| GA at delivery (weeks) | mean (SD) | 38.3 (2.1) | 38.8 (2.3) | 0.11 |
| Birth weight (gram) | mean (SD) | 3081 (638) | 3203 (694) | 0.17 |
| Birth weight <5th percentile | n (%) | 5 (4.9) | 12 (9.0) | 0.22 |
| APGAR <7 at 5 minutes | n (%) | 3 (2.9) | 7 (5.3) | 0.52 |
| NICU admission | n (%) | 2 (1.9) | 6 (4.5) | 0.47 |
delivery (mean 38.3 weeks (2.1) vs 38.8 weeks (2.3) p = 0.11), birth weight < 5th centile (4.9 vs 9.0%, p = 0.22), and admission to neonatal intensive care unit (1.9 vs 4.5%, p = 0.47).

4. Discussion

4.1. Main findings

We studied the use of a novel care path with telemonitoring of blood pressure and preeclampsia symptoms in a high-risk pregnant population. Our findings show that this strategy allows a reduced antenatal visit schedule, with fewer ultrasound assessments and antenatal hypertension-related admissions. However, evaluation was by comparison with a retrospective group without telemonitoring or a fixed antenatal visit schedule. In our sample, no differences were found in adverse maternal or perinatal outcomes between the two strategies.

4.2. Comparison to the literature and interpretation

The NICE guideline on antenatal care recommends more frequent blood pressure monitoring for those at risk of HDP and several others mention self-monitoring as a useful addendum to antenatal care [7,16]. A recent individual patient data meta-analysis of 758 subjects found an insignificant difference between clinic readings and self-monitored blood pressure values [17]. Based on this evidence, our threshold for alerts was set at 140/90 mmHg to be of clinical importance.

Recent literature describes a variety of monitoring strategies for women with a higher risk of hypertension in pregnancy [18–21]. In general, reduction of antenatal visits with help of out-of-office self-measurements, as found in our study, are in line with several other studies. One retrospective study of blood pressure telemonitoring for diagnosed hypertension in pregnancy showed a reduction of antenatal visits and admissions [18]. Two case-control studies started blood pressure self-monitoring in women with diagnosed hypertension, without telemonitoring but providing written instructions to patients when to contact the hospital [19,20]. Starting self-monitoring at 30–36 weeks of gestation, fewer visits were required with self-monitoring compared to a retrospective group with traditional care, in both studies. More importantly, the shift from hospital to home care did not seem to negatively affect pregnancy outcomes, although study sample sizes were likely not large enough to determine this [18–20]. One other prospective study started telemonitoring at start of pregnancy but did not include a control group for comparison of results [21]. There is conflicting data on the rate of labour induction in the literature. As for our study, induction of labour was more frequently started in the SAFE@HOME group, however hypertension as the main reason for induction of labour was similar between groups.

Our study differed from the described studies on several points. Our population of women, at risk of preeclampsia but without complications in first trimester, started telemonitoring early in pregnancy (mean 17.9 weeks of gestation) instead of starting at 30–36 weeks. Also, a symptom checklist was included within the platform. This combination proved to be beneficial for the full course of pregnancy. Absence of both hypertension and symptoms requires no further action, while symptoms in case of hypertension indicate need for evaluation.

4.3. Strengths and limitations

Our digital platform is one of the first to combine both blood pressure and symptom reporting, used with a reduced visit schedule. Prior to the study start, we validated the blood pressure monitor and carried out a feasibility study to test the Bluetooth-connected platform [12,14]. Eligible candidates were willing to participate in tele-monitoring, which is reflected in the high consent rate. Only 2/109 participants were transferred to standard care because of non-compliance.

A limitation of this study is the comparison to a retrospective control group, which is likely to have caused selection bias. The greater proportion of included women with kidney disease in the SAFE@HOME group adds to heterogeneity, because of the specific etiology of kidney disease as an increased risk factor for preeclampsia. This might limit generalizability of results.

Our study was not powered adequately to draw conclusions regarding adverse perinatal outcomes and therefore, future studies with substantial sample size would be needed.

Lastly, the studied strategy is a combination of both a digital health platform for remote monitoring and a reduced visit schedule. It is unknown whether the implementation of either of these components of the intervention individually would result in a similar effect on healthcare consumption and adverse outcomes.

4.4. Future implications

Our results imply that use of telemonitoring at home of blood pressure and preeclampsia symptoms in high risk pregnancies allows for fewer antenatal visits, notably after 34 weeks of gestation. The use of home measurements did not lead to an increase in health care consumption. Increased experience and compliance of obstetric care professionals to the new strategy may enhance the reduction of care use in the future.

Several implications of blood pressure telemonitoring in pregnancy still need evaluation. Before widespread use of telemonitoring, more evidence is needed from larger prospective studies. Studied groups should include both women at risk of hypertension or preeclampsia at start of pregnancy, as well as those with established gestational hypertension or mild preeclampsia [22]. Current knowledge gaps include the safety and impact of telemonitoring on (early) detection and/or prediction of complications as well as its effect on subsequent interventions as medication use and hypertension control, induction of labour, optimal administration of corticosteroids.

In general, digital health has the potential to have profound cost-saving effects because of the decline in visits, admissions, travel time, and work absence [23]. Women of reproductive age are interested in digital health, as shown by their frequent use of smartphones and pregnancy apps [24,25]. In future digital health studies of in pregnancy, use of healthcare services should be assessed too. Alongside its medical effects, cost-effectiveness must be evaluated before implementation of digital health in pregnancy care. The latter may also contribute to reimbursement of digital care [26,27].

5. Conclusion

Use of a digital health platform for blood pressure and symptom telemonitoring allows for fewer antenatal visits and ultrasound assessments in pregnancies at risk of preeclampsia. In this study there was no increase of adverse maternal and neonatal outcomes as compared to the control group. Larger prospective studies on telemonitoring in pregnancy are needed for evaluation of perinatal safety outcomes and cost-effectiveness.

Contribution to authorship

JFH, ATL, JCT and MNB designed the study. JFH, ATL, JHJ and MNB were responsible for the acquisition and interpretation of the data. JFH and MNB drafted the manuscript. All authors edited and revised the manuscript. All authors have read and approved the final version of the manuscript.

Details of ethics approval

This study was submitted to the Medical Ethics Committee of the University Medical Center in Utrecht (17/424). The committee judged
that the Dutch Medical Research Involving Human Subjects Act (WMO) did not apply to this study.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.preghy.2020.07.006.

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