Full length article

The impact of a remote monitoring program on the prenatal follow-up of women with gestational hypertensive disorders

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A B S T R A C T

Objectives: In 2015, we showed the value of a remote monitoring (RM) follow-up program for women diagnosed with gestational hypertensive disorders (GHDs) compared with women who received conventional care (CC). We want to confirm or refute the conclusions drawn in 2015, by including data from 2016.

Study design: A two year retrospective study in which all women diagnosed with GHD, who underwent prenatal follow-up at the outpatients prenatal clinic of Ziekenhuis Oost-Limburg (Genk, Belgium) during 2015 and 2016, were included. Of the 320 women diagnosed with GHD, ninety (28.13%) were monitored with RM. The other 230 (71.88%) GHD pregnancies were monitored with CC. Differences in continuous and categorical variables in maternal demographics and characteristics were tested using Unpaired Student’s t-test or Mann Whitney U test and the c\textsuperscript{2} test. Both a univariate and multivariate analysis were performed for analyzing prenatal follow up and gestational outcomes. All statistical analyses are done at nominal level \(a = 0.05\).

Results: The RM group had more women diagnosed with gestational hypertension but less with pre-eclampsia when compared to the CC group (69.77% versus 42.79% and 19.77% versus 44.19% respectively). In both uni- and multivariate analyses, the RM group had, when compared to the CC group, less prenatal admission (51.62% versus 71.63%), less prenatal admissions until the moment of the delivery (31.40% versus 57.67%), less induced starts of the birth process (43.00% versus 32.09%), more spontaneous starts of the birth process (32.86% versus 46.51%), more births after 37 weeks of gestational age in pregnancies complicated with gestational hypertension (91.67% versus 53.33%) and pregnancies complicated with pre-eclampsia (58.82% versus 53.33%). In multivariate analysis, a reduction in total number of prenatal visits was visible in the RM group when compared to the CC group (b = \(-1.76;\ CI = \(-2.74-0.77\)). Only in the univariate analysis was the mean gestational age at delivery between 34 and 37 weeks of gestation in pregnancies complicated with gestational hypertension higher in the CC group versus the RM group (35 w 4/7 (\(\pm 0.49\)) versus 34 w 6/7 (\(\pm 0.00\)).These conclusions were almost the same as in the analyses of 2015, except (1) there wasn’t a difference anymore in NICU admissions between the RM and CC group in the analyses of 2015–2016 and (2) a significant decrease in total number of visits is reported in the RM group in the dataset of 2015–2016, which wasn’t visible in the dataset of 2015.

Conclusions: This study demonstrates that RM provides opportunities to offer timely interventions to pregnant women who require them.

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Introduction

Gestational hypertensive disorders (GHDs), including gestational hypertension and pre-eclampsia, are some of the leading causes of maternal morbidity and mortality [1,2]. Gestational hypertension is characterized by the new onset of hypertension...
(≥140/90 mmHg systolic blood pressure or ≥100 mmHg diastolic blood pressure) after 20 weeks of gestation. When this hypertension is combined with proteinuria (spot urine protein/creatinine ratio ≥30 mg/mmol or ≥300 mg/day or at least 1 g/L on dipstick testing), a diagnosis of pre-eclampsia is made [3]. The commonest management strategy for GHD in Belgium is admission to a prenatal observation unit for diagnostic and therapeutic follow-up before the induction of labor or discharge. In severe cases, premature birth is indicated [4].

As part of the Hasselt University and Limburg Clinical Research Program (LCRP), Ziekenhuis Oost-Limburg (Genk, Belgium) initiated a remote monitoring (RM) program in January 2015 for women at risk of GHD. RM is a relatively new approach (dating back to the early 1990s), which facilitates patient management at home [5]. It can be broadly defined as the use of telecommunication technologies to facilitate the transmission of medical information and services between health-care providers and patients. The use of this two-way telecommunication technology, multimedia, and computer networks to deliver or enhance the delivery of health care is a growing trend internationally [6].

The first clinical results of RM in GHD, obtained retrospectively during the year in which remote communication between hospital doctors or midwives and pregnant women at home was technically installed, were published in 2016 [7]. A second pilot project was performed in which more patients were included in both the prenatal RM follow-up program and in the conventional care (CC) program during a study period of 2 years. In this paper, we report the results of this RM program to confirm or refute the conclusions of the analysis published in 2016.

Material and methods

Subjects

All women diagnosed with GHD who underwent prenatal follow-up at the outpatient prenatal clinic of Ziekenhuis Oost-Limburg (Genk, Belgium) during 2015 and 2016 were included. Women received RM at the behest of the responsible obstetrician because of their high-risk status or after discharge from the prenatal observation ward. The criterion to initiate RM was GHD at a gestational age of ≥10 weeks when intensive follow-up until delivery was desirable. Women at a gestational age of <10 weeks, or women who did not give their informed consent received CC.

Between January 1, 2015 and December 31, 2016, 4142 women underwent (at least a part of) their prenatal care and/or delivery at Ziekenhuis Oost-Limburg: 320 (7.73%) were diagnosed with GHD, 90 (28.13%) of whom received CC together with RM, and the remaining 230 (71.86%) women with GHD did not receive RM, but only CC.

Interventions in the RM group

Women consenting to RM received obstetric surveillance via a wireless blood-pressure monitor, weight scale, and activity tracker. Pregnant women participating in the prenatal RM follow-up program were asked to make one blood-pressure measurement in the morning and one in the evening and one weight measurement weekly, and to wear the activity tracker day and night until delivery or hospital admission. The blood-pressure monitors which were used are CE-approved and comply with the European regulations. These devices were clinically validated in ZOL before given them to the women who used them at home.

The data from the monitoring devices were transmitted to an online dashboard developed by the Mobile Health Unit of the University of Hasselt. Predetermined alarm signals were set. One midwife was responsible for remote follow-up of all the transmitted data at the online dashboard, by distinguishing normal and alarm signals for systolic blood pressure > 140 mmHg, diastolic blood pressure > 90 mmHg, and weight gain > 1 kg/day. Alarm events were communicated to the obstetrician-in-charge to discuss management options before the patient at home was contacted and instructed. The types of interventions were: [1] expectant management; [2] ambulatory blood sampling and 24 h urine collection at home; [3] adjustment of antihypertensive therapy and/or physical activity; [4] admission to the prenatal ward; and [5] induction of labor. The therapeutic interventions were based on local management strategies.

The Ziekenhuis Oost-Limburg Medical Ethics Committee approved the study.

Maternal demographic factors

The maternal demographic factors and characteristics of the patients in the RM group were collected at study entry. In the CC group, these data were obtained by manual searches through the electronic medical records.

Primary outcome: prenatal follow-up

The total number of prenatal consultations was measured from the start of the pregnancy: ultrasound scans, cardiotocography, admission to the prenatal ward, total days of hospitalization, and the number of admissions until delivery. These data were collected retrospectively from the electronic medical records after the delivery of the women in both the RM and CC groups. These data were checked with the hospital administration and/or billing records.

Secondary outcome: delivery outcomes

The maternal parameters collected at birth were gestational age at delivery, intended mode of delivery, and mode of delivery. The neonatal outcomes collected were birth weight, Apgar score at 1 min and 5 min, and number of admissions to the NICU.

Statistical analysis

Differences in continuous and categorical variables in the maternal demographic factors and characteristics were tested with unpaired Student’s two-sample t test or the Mann–Whitney U test and a \( \chi^2 \) test. Both univariate and multivariate analyses were performed to analyze the prenatal follow-up and gestational outcomes. Beta coefficients and 95.0% confidence intervals were calculated for the multivariate analysis. All statistical analyses are performed with a nominal level of \( \alpha = 0.05 \). The statistical analyses were performed with SPSS release 24.0 (IBM® SPSS® Inc., Chicago, Illinois, USA).

Results

Participant demographics

Of the 4142 women who delivered in Ziekenhuis Oost-Limburg in 2015 and 2016, 320 (7.73%) of them were diagnosed with GHD and had prenatal care and/or gave birth at this hospital. Ninety (28.13%) of the GHD pregnancies were monitored with RM. Of these, four (1.25%) were excluded from the analysis because of missing data, so 86 (26.86%) were eligible for analysis. The other 230 (71.88%) GHD pregnancies were monitored with CC. Of these, 15 (4.69%) women were excluded because of missing data, so 215
(67.19%) were eligible for analysis. Fig. 1 shows the study population in a flow chart.

Table 1 shows the maternal demographic factors and characteristics of the women with GHD. In the RM group, there were more women with immunological disorders (2/86 [2.30%] versus 2/215 [0.90%), respectively) and fewer smokers than in the CC group (2/86 [2.30%] versus 23/215 [10.70%), respectively).

Prenatal follow-up: comparison of RM and CC

Data on the prenatal follow-up are shown in Table 2. In the multivariate analysis, the total number of prenatal visits was lower in the RM group than in the CC group (b = −1.76). The number of prenatal admissions (44/86 [51.16%] versus 154/215 [71.63%], respectively, b = −1.23) and prenatal admissions until delivery (27/86 [31.40%] versus 124/215 [57.67%], respectively, b = −1.24) were lower in the RM group than in the CC group in both the uni- and multivariate analyses. In both the uni- and multivariate analysis, the prevalence of gestational hypertension was higher in the RM group than in the CC group (60/86 [69.77%] versus 92/215 [42.79%], b = 0.24), but the prevalence of pre-eclampsia was lower in the RM group (17/86 [19.77%] versus 95/215 [44.19%], b = −0.23).

To investigate the influence of the maternal demographic factors and characteristics on the prenatal follow-up, a multiple linear regression analysis and multivariate logistic regression analysis were performed. A detailed overview of these data is given in Supplementary file 1 in the Supplementary Appendices.

Delivery outcomes: comparison of RM and CC

The delivery outcomes are shown in Tables 3–5. In both the uni- and multivariable analyses in Table 3, the RM group showed a higher number of spontaneous births than the CC group (43/86 [50.00%] versus 69/215 [32.09%], respectively, b = 0.86). The number of inductions was also lower in the RM group than in the CC group (28/86 [32.56%] versus 100/215 [46.51%], respectively, b =

Table 1

<table>
<thead>
<tr>
<th>Maternal demographic factors and characteristics</th>
<th>RM group (n = 86)</th>
<th>CC groups (n = 215)</th>
<th>Statistical significance (2 – tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (years)</td>
<td>30.97 (±5.61)</td>
<td>30.53 (±5.17)</td>
<td>P = 0.25</td>
</tr>
<tr>
<td>Pre-pregnancy weight (kg)</td>
<td>73.76 (±15.88)</td>
<td>77.57 (±18.87)</td>
<td>P = 0.08</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>165.54 (±6.46)</td>
<td>165.60 (±13.70)</td>
<td>P = 0.24</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.79 (±53.36)</td>
<td>28.38 (±6.67)</td>
<td>P = 0.05</td>
</tr>
<tr>
<td>Primigravida (%)</td>
<td>52 (60.47%)</td>
<td>142 (66.05%)</td>
<td>P = 0.33</td>
</tr>
<tr>
<td>Concomitant diseases (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Cardiovascular disorders (%)</td>
<td>1 (1.16%)</td>
<td>4 (1.86%)</td>
<td>P = 0.67</td>
</tr>
<tr>
<td>- Blood coagulation disorder (%)</td>
<td>2 (2.32%)</td>
<td>2 (0.93%)</td>
<td>P = 0.34</td>
</tr>
<tr>
<td>- Endocrine disorders (%)</td>
<td>2 (2.32%)</td>
<td>14 (6.51%)</td>
<td>P = 0.82</td>
</tr>
<tr>
<td>- Immunological disorders (%)</td>
<td>2 (2.32%)</td>
<td>2 (0.93%)</td>
<td>P = 0.04</td>
</tr>
<tr>
<td>Smoking (%)</td>
<td>2 (2.32%)</td>
<td>23 (10.70%)</td>
<td>P = 0.02</td>
</tr>
<tr>
<td>GA first visit (week)</td>
<td>10.51 (±6.11)</td>
<td>10.60 (±5.52)</td>
<td>P = 0.58</td>
</tr>
</tbody>
</table>

RM = remote monitoring, CC = conventional care, GA = gestational age; data are means (± SD) or percentages (numbers).
and hypertensive analysis (P<0.01). Prenatal admission until delivery (%) showed a lower incidence of pre-eclampsia but an increased incidence of gestational hypertension in the group of women on the prenatal RM program than in the women who received CC. Compared with the CC group, the women in the RM group had fewer admissions to the prenatal ward and fewer hospitalizations until the moment of delivery, more births after 37 weeks of gestational age in pregnancies complicated with gestational hypertension (91.67% [55/60] vs. 53.33% [61/118], b = 0.26) and pregnancies complicated with pre-eclampsia (58.82% [10/17] vs. 53.33% [40/75], b = 0.22). Only in the univariate analysis was the mean gestational age at delivery between 34 and 37 weeks of gestation in pregnancies complicated with gestational hypertension higher in the CC group versus the RM group (35.4 ± 0.49 vs. 34.4 ± 0.07; p = 0.008) (Table 5).

To investigate the influence of the maternal demographic factors and characteristics on the prenatal follow-up, a multiple linear regression analysis and multivariate logistic regression analysis were performed. A detailed overview of these data is given in Supplementary file II in the Supplementary Appendices.

Comment

Principal results

We sought to confirm or refute the conclusions of a retrospective analysis of data from 2015. The findings of the present study include a lower incidence of pre-eclampsia but an increased incidence of gestational hypertension in the group of women on the prenatal RM program than in the women who received CC. Compared with the CC group, the women in the RM group had fewer admissions to the prenatal ward and fewer hospitalizations until the moment of delivery, more births after 37 weeks of gestational age in pregnancies complicated with gestational hypertension and pregnancies complicated with pre-eclampsia in both univariate analyses. The women in the RM group also had fewer prenatal visits than the women in the CC group, but only in the multivariate analysis. In both analyses, spontaneous deliveries were more likely and inductions less likely in the RM group than in the CC group. Only in the univariate analysis was the mean gestational age at delivery between 34 and 37 weeks of gestation in pregnancies complicated with gestational hypertension higher in the CC group versus the RM group.

Our conclusions are basically the same as the conclusions drawn from the dataset of 2015. Only two distinctions can be made: [1] the newborns of the women who received RM during their pregnancies in 2015 were less likely to be admitted to the NICU than the newborns of the women who received CC, and this discrepancy is not evident in the 2015–2016 analysis; and [2] there
was no difference in the total number of prenatal visits between the women of the RM and CC groups in 2015. In contrast, in the present analysis, the women on the RM program had fewer prenatal visits than the women who received CC.

**Strengths and limitations**

One of the major strengths of this study is its design: data were collected over a study period of 2 years, and a retrospective design was used. Many data were collected during this time on a prenatal RM program for the follow-up of GHD, one of the commonest pregnancy complications, although its prevalence is only 10% [8]. It is hard to undertake a prospective investigation of this topic because the prevalence of the disorder is often unpredictable. A retrospective design may not be the first choice for a study, but it was the best way to collect data on this topic over a period of 2 years. Another strength of our study is that ours is the only hospital in the province of Limburg (Flanders, Belgium) with its own prenatal ward. Pregnant women with an elevated risk of developing GHD, or who develop this disorder unexpectedly during their pregnancy, are referred to our hospital for further follow-up. In this way, we have a lot of information about prenatal follow-up in this patient population and our hospital has close associations with the other hospitals in Limburg, so it is easy to exchange missing data. Therefore, all the patients received antenatal care in accordance with uniform local management protocols and we had an almost complete dataset.

Our study also had three main limitations. First, by collecting data retrospectively, we could not exclude selection bias. Second, there were small differences in the maternal demographic factors and characteristics. More women smoked during their pregnancy and fewer women had immunological disorders in the CC group.
than in the RM group. Although a multivariate analysis showed that these parameters did not influence our principal findings, smoking during pregnancy has adverse outcomes, although a reduced risk of developing of GHD in women who smoke has been demonstrated in many studies [4,9]. There is insufficient or conflicting evidence suggesting that immunological diseases influence the development of GHD [10–13]. The last limitation is that interference by family doctors or community midwives cannot be excluded.

Comparisons with previous trials

The retrospective study of an RM prenatal follow-up program for women with GHD, published in 2016, was to our knowledge the first study to report the value of this technology in obstetrics. Since the appearance of that publication, no new articles have been published about the value of an RM prenatal follow-up program for women with GHD. However, Marko et al. (2016) reported a feasibility study of the use of a mobile phone app and connected digital devices (weight scale and blood-pressure monitor) for women at risk for adverse pregnancy outcomes. They concluded that this system is feasible for prenatal care [13]. Several studies of RM programs that assist nonpregnant patients with hypertension to control their blood pressure have been reported. All of these have concluded that home monitoring of blood pressure is a reliable and promising method that can potentially contribute to blood pressure reduction [14–18]. Based on this literature, RM has already proven its utility for the management of hypertensive disorders outside pregnancy. In our study, we have demonstrated that RM also has value for hypertensive disorders during pregnancy.

Possible explanations and recommendations for further research

A possible explanation of the differences in admission to the prenatal observational ward and gestational outcomes observed in this study is that pre-eclampsia can result from gestational hypertension or essential hypertension [19–21]. RM makes it possible for caregivers to see abnormal events in pregnant women in their home contexts and to offer an intervention when necessary to prevent the worsening of the disease. Several studies have suggested that starting or adjusting an antihypertensive therapy can reduce the risk of developing severe hypertension or pre-eclampsia [22–25]. However, this is refuted by the study of Duley (2011), who demonstrated that an antihypertensive therapy can reduce the risk of severe hypertension, but not of pre-eclampsia [26]. Further investigation of the value of an antihypertensive therapy in preventing the exacerbation of GHD is recommended.

When pre-eclampsia is diagnosed, the only treatment that can be used to prevent further complications is the induction of labor [27]. More women were diagnosed with pre-eclampsia in the CC group, than in the RM group. This could explain the higher rate of inductions in the CC group. Gestational hypertension is not usually a reason to induce labor, and expectant management until a spontaneous labor is advised. This may explain the higher number of spontaneous births in the RM group.

Fewer prenatal visits were also observed in the RM group than in the CC group. Women with GHD who participated in the RM prenatal follow-up program were no longer required to visit the hospital in the prenatal period to monitor their blood pressure. Blood pressure can be monitored at home, under the remote supervision of a responsible caregiver. This new type of management can be a useful tool for caregivers in that it allows them to spend their time on pregnant women who really require their attention. However, caregivers will require time to get used to this type of management, which may explain why there was a reduction in the total number of prenatal visits in 2016, but not in 2015. Additionally, it would be interesting and valuable to perform a cost-effectiveness study. When RM has a positive cost-effectiveness rating, less-expensive care will improve gestational outcomes.

To conclude, a qualitative investigation of maternal satisfaction with the use of RM is recommended. A thorough qualitative analysis will allow a comprehensive understanding of patient satisfaction, and this information could be used to improve future technological designs. This may allow interventions to be adjusted to the target population and have positive effects on various domains, including patient compliance and birth experience.

Source of funding

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Conflict of interest

None.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found in the online version, at https://doi.org/10.1016/j.ejogrb.2018.02.015.

References


