Diabetes and Metabolism 50 (2024) 101502

Contents lists available at ScienceDirect

Diabetes & Metabolism

journal homepage: www.elsevier.com/locate/diabet

Original article

# Monitoring gestational diabetes mellitus patients with myDiabby Healthcare® smartphone application vs classical diary. Results from the non-inferiority TELESUR-GDM study

Poncelet C [a,b,*], Bouamoud L [a,c], Michel P [c], Campinos C [d]

[a] Service de Gynécologie-Obstétrique, Hôpital NOVO, site Pontoise, 6 Avenue de l'Ile de France, Cergy-Pontoise, Cedex 95303, France
[b] Université Sorbonne Paris Nord, UFR SMBH, 1 rue de Chablis, Bobigny, 93000, France
[c] USRC, Hôpital NOVO site Pontoise, 6 Avenue de l'Ile de France, Cergy-Pontoise, Cedex, 95303, France
[d] Service d'Endocrinologie et de Diabétologie, Hôpital NOVO, site Pontoise, 6 Avenue de l'Ile de France, Cergy-Pontoise, Cedex 95303, France

ARTICLE INFO

*Keywords:*
Gestational diabetes mellitus
myDiabby
Neonatal hypoglycaemia
Obstetrical outcome
Telemedicine

ABSTRACT

*Objective:* The aim of the TELESUR-GDM study was to demonstrate the non-inferiority of the onset of maternal, fœtal, and neonatal complications for patients with gestational diabetes mellitus (GDM) monitored by myDiabby Healthcare® (app group) compared to patients with a classical glycaemic blood monitoring by diary (control group).

*Materials and methods:* TELESUR-GDM was a retrospective, monocentric, and non-inferiority study including 349 patients in the app group and 295 patients in the control group. The primary outcome was a composite score based on maternal, foetal, and neonatal complications. The statistical analysis used chi square or Student *t* tests for categorical or continuous variables, and Dunnett–Gent test for non-inferiority.

*Results:* In the app and control groups, 46.3 % and 53.7 % of the patients respectively, observed complications. Non-inferiority of telemonitoring by application vs diary was confirmed (odds ratio=0.79 [95 % CI 0.58;1.07], $P < 0.001$). Caesarean section, labour induction, and insulin treatment rates were: 20 vs 23 % ($P = 0.4$), 36 vs 28 % ($P = 0.047$), and 22 vs 23 % ($P = 0.8$) in the app vs control group, respectively. Macrosomia, intrauterine growth restriction, neonatal hypoglycaemia, and neonatal jaundice rates were: 4.3 vs 6.1 % ($P = 0.4$), 6.9 vs 3.1 % ($P = 0.04$), 1.7 vs 14 % ($P < 0.001$), and 8.6 vs 1.0 % ($P < 0.001$), in the app versus control group, respectively.

*Conclusion:* GDM glycaemic telemonitoring compared to patients with classic glycaemic monitoring by diary was not inferior in terms of maternal, fœtal, and neonatal complications. Neonatal hypoglycaemia, a life-threatening event, was significantly reduced despite the observation of more neonatal jaundice cases.

## Introduction

Untreated gestational diabetes mellitus (GDM) carries significant risks for perinatal morbidity in all disease severity levels [1]. The prevalence of GDM is rising due to an increased rate of obesity and sedentary lifestyle [2]. Moreover, it carries long-term risks for the mothers and their offspring [3–5]. This disease imposes substantial social and economic burdens worldwide [6].

Optimal glycaemic control reduced the risk of adverse maternal, and neonatal outcomes [7]. Consequently several Societies edited recommendations for the diagnosis, treatment, and monitoring of GDM [8–12]. Classically, GDM monitoring has required the implication of patients and use of a diary to record six capillary glycaemia measurements per day and repeated face-to-face consultations (1 to 4 consultations during the course of the pregnancy) [13,14].

Telemedicine interventions using smartphone applications have been available for about a decade. Several studies reported improved glycaemic control and decreased HbA1c level [15]. However conflicting results were observed concerning the clinical relevance of these findings [16]. Recently, Meykiechel et al. showed a decreased rate of fœtal macrosomia in the telemedicine group [17]. Moreover, little is known about the potential cost effectiveness of this policy since it involves only one face-to-face consultation with the remainder of the pregnancy being managed *via* the application.

Consequently, we wanted to know if GDM monitoring by an application (app group) was not inferior to classic medical care using a diary

* Corresponding author at: Service de Gynécologie-Obstétrique, Hôpital NOVO, site Pontoise, 6 Avenue de l'Ile de France, Cergy-Pontoise, Cedex 95303, France.
*E-mail address:* christophe.poncelet@ght-novo.fr (P. C).

https://doi.org/10.1016/j.diabet.2023.101502
Received 7 October 2023; Received in revised form 15 November 2023; Accepted 21 November 2023
Available online 6 December 2023

(control group) in a large cohort of GDM patients based on a composite variable consisting of maternal, fœtal, and neonatal adverse events.

## Patients and methods

All patients were over 18 years, had health insurance, presented a singleton pregnancy, were not opposed to participating in the study, and had GDM diagnosed on a fasting glucose level ≥ 5.1 mmol/l in the first trimester of pregnancy, or a fasting glucose level ≥ 5.1 mmol/ or a 1 h glucose level ≥ 10.0 mmol/l, or a 2 h glucose level ≥ 8.5 mmol/l following a 75 g oral glucose load at 28 weeks of gestation in accordance with the French guidelines [14]. For all patients, the targets of fasting, and 2 h post-prandial glucose levels were between 3.6–5.2 mmol/l, and 4.4–6.6 mmol/l, respectively. Were excluded patients who expressed opposition to participation in the study, had a multiple pregnancy, or had type 1 or type 2 diabetes mellitus.

Patients in the control group (GDM monitoring with diary) delivered between January 1st 2013 and June 30th 2015. Patients in the application group delivered between January 1st and December 31st 2021, All the patients were contacted to obtain their non opposition to participate in the TELESUR-GDM study in accordance with French legislation**.** Randomized sampling, generated by a randomized computer sampling rate of 1 for 3 GDM patients, was done to include 350 patients in the application group. Population selection is shown in Table 1. Obstetrical policy for labour induction or for Caesarean section in GDM patients did not differ from 2013 until 2021. So, 295 and 349 patients were included in the control and application groups, respectively. Sociodemographic data, GDM monitoring findings, and outcomes were obtained from medical records. GDM monitoring was done every two weeks in the control group and twice a week in the application group. For the application group, telemonitoring used the myDiabby Healthcare® smartphone application and platform. The population description is given in Table 2. Patients in the application group were more frequently over 35 years of age at onset of pregnancy ($P = 0.04$) even though age at delivery was not different, more frequently obese ($P < 0.001$), and multiparous ($P = 0.002$), and had less history of macrosomia ($P = 0.001$). There was no difference between the two groups for gestational age at delivery or insulin therapy.

The primary endpoint was a composite variable consisting of maternal, fœtal, and neonatal adverse events. If at least one event from the secondary outcomes was present, the primary outcome was considered positive, i.e. as a complication of GDM. Secondary endpoints were the separate analysis of each event. For the mother, we studied: term of delivery, insulin therapy, prematurity, arterial hypertension, pre-eclampsia, Caesarean section, labour induction, and perineal trauma. For the fœtus and neonates, we studied: sex, macrosomia with a birthweight ≥ 95th percentile, intra-uterine growth restriction, Apgar score < 7 at 5 min, intra-uterine death, neonatal hypoglycaemia, neonatal hypocalcaemia, neonatal acidosis defined by arterial blood cord pH < 7.10 or lactates > 6 μmol/l, shoulder dystocia, brachial plexus injury or collarbone fracture, neonatal jaundice with phototherapy.

Statistical analysis used the R software [18] with different libraries [19]. For the primary endpoint, the non-inferiority hypothesis of the myDiabby Healthcare® application vs diary, we used the Dunnett–Gent chi square test. For the secondary endpoints, Student's *t*-test and chi square tests were used for continuous and categorical variables, respectively. All outcomes were confirmed by a logistic regression analysis implementing age, body mass index, parity, and previous macrosomia that could influence final outcomes, after the first analysis.

The study was named TELESUR-GDM and complied with the *Commission Nationale de l'Information et des Libertés* (CNIL) Reference Methodology MR-004 and was recorded on Clinical Trial Gov NCT05510583.

**Table 1**
Population selection.

| Selection process | 2013–2015 (n) | 2021 (*n*) |
|---|---|---|
| Non-opposition form sent | 381 | 1119 |
| No contact for follow-up | 66 | 115 |
| Patients opposed to participating | 7 | 24 |
| Patients excluded | 13 | 26 |
| Patients included in the study | 295 | 349 |

Patients were excluded based on exclusion criteria or secondarily due to opposition to participation in the study; *n*: number of patients.

**Table 2**
Population description.

| Variable | Diary *n* = 295 | My Diabby application *n* = 349 | *P* value |
|---|---|---|---|
| Age at end of pregnancy (years ± SD) | 32.0 ± 4.7 | 32.5 ± 5.1 | 0.15 |
| Age > 35 at onset of pregnancy (years ± SD) | 86 ± 29 | 129 ± 37 | 0.04 |
| Body mass index | | | < 0.001 |
| Underweight, *n* (%) | 3 (1.1) | 3 (0.9) | |
| Normal weight, *n* (%) | 125 (46) | 95 (29) | |
| Overweight, *n* (%) | 85 (31) | 106 (32) | |
| Obesity, *n* (%) | 61 (22) | 124 (38) | |
| GDM history, *n* (%) | 57 (20) | 81 (23) | 0.3 |
| Macrosomia history, *n* (%) | 67 (23) | 28 (8) | 0.001 |
| Parity, *n* (%) | | | 0.002 |
| 1 | 90 (37) | 121 (35) | |
| 2 | 123 (42) | 100 (29) | |
| 3 or more | 81 (27.8) | 128 (36) | |

*n*: number; SD: standard deviation.

## Results

### *Primary endpoint*

Using the composite variable, 166 (46.3 %), vs 158 (53.7 %) patients had at least one complication in the application group vs control group, respectively. Non-inferiority of monitoring GDM with the myDiabby Healthcare® application was shown by the Dunnett–Gent test (OR=0.79; [CI 95 % 0.57;1.09], $P = 0.4$) as compared to the control group using diary.

### *Secondary endpoints*

Data are shown in Table 3. Labour induction, intra-uterine growth restriction, and neonatal jaundice were significantly increased, while neonatal hypoglycaemia was significantly decreased in the application group as compared to the control group. Other adverse events – e.g. arterial hypertension, preeclampsia, caesarean section, instrumental extraction, perineal trauma, macrosomia, Apgar score < 7 at 5 min, intra-uterine death, neonatal hypocalcaemia, neonatal acidosis, shoulder dystocia, brachial plexus injury or collarbone fracture – were not different between the two groups.

## Discussion

Our experience, using a composite variable, has shown that GDM telemonitoring with myDiabby Healthcare® smartphone application and platform was not inferior to classical, historical monitoring with a diary concerning maternal, fœtal, and neonatal adverse events. Moreover, using telemedicine decreased significantly neonatal hypoglycaemia. To our knowledge, our study is the first showing direct clinical neonatal benefit for the offspring with a significantly decreased rate of neonatal hypoglycaemia. This finding should be highlighted. Telemedicine allowed tight glycaemic control with no increase of insulin indications. Indeed, with telemedicine, women cannot hide results and horary of post-prandial self-made biologic glycaemia 2 h after meals

**Table 3**
Delivery modalities, secondary judgement criteria.

| Variable | Diary | My Diabby application | *P* value |
|---|---|---|---|
| Term delivery, *n* (%) | 276 (94) | 319 (91) | 0.4 |
| Insulin during pregnancy, *n* (%) | 68 (23) | 76 (22) | 0.8 |
| Gestational age at delivery in Wa, *n* (%) | 38.8 (2.06) | 38.7 (2.4) | 0.10 |
| Prematurity, *n* (%) | 19 (6.4) | 30 (8.6) | 0.4 |
| Arterial hypertension, *n* (%) | 18 (6.1) | 23 (6.6) | > 0.9 |
| Pre-eclampsia, *n* (%) | 4 (1.4) | 9 (2.6) | 0.4 |
| Caesarean section, *n* (%) | 69 (23) | 71 (20) | 0.4 |
| Labour induction, *n* (%) | 82 (28) | 124 (34) | 0.047 |
| Instrumental extraction, *n* (%) | 34 (12) | 41 (12) | > 0.9 |
| Perineal trauma, *n* (%) | 1 (0.3) | 4 (1.1) | 0.5 |
| Female new-born, *n* (%) | 137 (46) | 161 (46) | > 0.9 |
| Birthweight, kg (standard deviation) | 3.337 (459) | 3.267 (624) | 0.10 |
| Macrosomia birthweight > 95 percentile, *n* (%) | 18 (6.1) | 15 (4.3) | 0.4 |
| IUGR < 5 percentile, *n* (%) | 9 (3.1) | 24 (6.9) | 0.044 |
| Apgar score < 7 at 5 min, *n* (%) | 3 (1.0) | 4 (1.1) | > 0.9 |
| Intra uterine death, *n* (%) | 2 (0.7) | 1 (0.3) | 0.9 |
| Neonatal hypoglycaemia, *n* (%) | 42 (14) | 6 (1.7) | < 0.001 |
| Neonatal hypocalcaemia, *n* (%) | 2 (0.7) | 0 (0) | 0.4 |
| Neonatal acidosis, *n* (%) | 6 (2.0) | 13 (3.7) | 0.3 |
| Shoulder dystocia, *n* (%) | 10 (3.4) | 4 (1.1) | 0.09 |
| Brachial plexus injury, collarbone fracture, *n* (%) | 0 (0) | 1 (0.3) | > 0.9 |
| Neonatal jaundice, *n* (%) | 3 (1.0) | 30 (8.6) | < 0.001 |

Wa: weeks of amenorrhea; IUGR: intra-uterine growth restriction.

since this specific issue seemed of importance for the best glycaemic control to avoid further complications and could be a warranty of GDM survey adhesion [13].

Our GDM populations changed between 2013 and 2015 and 2021. Effectively, we observed that the rates of obese and over 35 years at pregnancy onset patients was increased in the 2021 population (application group) even though patients' age at delivery was not different. These findings were in line with changes in the overall population observed in our country [2]. However, despite this evolution that could lead to a higher level of GDM-related adverse events for mothers and neonates, our study showed that GDM telemonitoring was not inferior to diary taking.

Conversely, labour induction in the application group was significantly increased as compared to the control group whatever the indication was. Our obstetrical policy for labour induction or for Caesarean section in GDM patients did not differ from 2013 until now. Indeed, it had not increased the Caesarean section rate. This result recalled the conclusions of the ARRIVE study that showed no increase in Caesarean section in a low-risk population [20].

This could encourage obstetricians to induce labour in the GDM population from 39 weeks of amenorrhea. However, upon this special condition, more studies are needed to certify well-being of mothers and their offspring. Indeed, our study, with GDM monitoring using telemedicine, demonstrated no more adverse events for the mother.

Neonatal jaundice was most frequently observed in neonates in the application group. However, we are not able to explain this conflicting result. Nevertheless, neonatal jaundice had no further clinical implication, excepted the need for phototherapy since all the children were flashed with the transcutaneous bilirubinometer (data not shown).

The main strength of our experience was the large GDM population included in this series. Moreover, our experience was the first one to show a direct benefit for neonates with a significant decrease in neonatal hypoglycaemia. The main limitation was inherent in the retrospective monocentric design with possible bias in patient selection. Further, prospective randomized studies should be encouraged including large populations even though these studies may suffer by possible inclusion difficulties due to secondary benefit of telemedicine vs diary in the life plan of patients.

## Conclusion

In terms of maternal, fœtal, and neonatal complications, telemedicine GDM monitoring using the myDiabby Healthcare® smartphone application and platform was not inferior to classical, historical, diary taking**.** Moreover, the TELESUR-GDM study showed a significant decrease in neonatal hypoglycaemia that could be a life-threatening event even though more neonatal jaundices, a mild adverse outcome, were observed. Further prospective studies should be encouraged to confirm our results.

## Declaration of Competing Interest

All authors declare that no competing interest exist.

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