

# **Diabetes and Technology: Continuous Glucose Monitoring among Pregnant Women in Real** Time

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Abstract

The objective of this paper is to assess if real-time intermittent Continuous Glucose Monitoring (CGM) helps to improve the control of glycemic and outcome of pregnancy in women with diabetes. A total of 123 women with type 1 diabetes and 31 women with type 2 diabetes respectively were used at random in the Continuous Glucose Monitoring for a total of 6 days at different stages of pregnancy. Results revealed that intermittently using real-time Continuous Glucose Monitoring in pregnancy plus plasma glucose which is self-monitored does not really help to improve the control of glycemic or outcome of pregnant women with diabetes.

# **Keywords**

Diabetes, Glucose, Monitoring, Pregnancy, Technology

# 1. Introduction

Of the complications that a pregnant woman may face, one of the most serious ones is gestational diabetes. While some women are informed about the disease, substantial majorities lack the relevant information and this compromises not only their lives but also the life of the unborn baby. Diabetes in expectant women is major as a result of outcomes that are adverse of perinatal which are distributed largely to hyperglycemia maternity as well as morbidity perinatal, preterm delivery and large gestational infants. The large gestational infants are a very high risk of birth trauma to mothers with diabetes as well as transient tachypnea and hypoglycemia neonatal. The major setback in striving towards glycemic maternal control is the severe hypoglycemia risk. Real-time Continuous

Glucose Monitoring (CGM) is used to measure glucose in the interstitial in the fashion that is ongoing and helps offer a chance of hypoglycemic.

## 2. Diabetes and Technology

## 2.1. Management of Diabetes in Pregnancy

Participants who were in the intervention arm were given the intermittent Continuous Glucose Monitoring for about 6 days at their very first visit for pregnancy which was at 2 months. This was then followed by those at 12, 21, 27 and lastly 33 weeks beside the routine care during pregnancy [1]. Women were asked to continuously use the real-time Continuous Glucose Monitoring more so on the hypoglycemia unawareness cases. The real-time Continuous Glucose Monitoring was not charged irrespective of the number of periods of monitoring. In the control arm, blinded real-time Continuous Glucose Monitoring was not carried out [2].

During the first visit, allocation of women to intervention where they have received education about sensor insertion as well as the system of maintenance the basis of one on one for about 1 to 2 hours by a well-trained caregiver of diabetes [3]. Women were given instructions to keep performing self-monitored plasma measurements of glucose just as it is recommended and to ensure they verify their real-time Continuous Glucose Monitoring glucose values accuracy. Women who had real-time Continuous Glucose Monitoring alarms together with a subsequent glucose plasma of <4.0 mmol/L were advised to supplement their carbohydrate intake [4].

Each and every woman received a phone call which was scheduled after the first insertion of the sensor. Contacting of the clinic by the patients was encouraged at any time they felt like and visits were paid to them during the weekdays. Most women preferred that the insertion of the sensor be in the abdominal skin [5]. However, in late pregnancy during caesarean or labor, some preferred it to be inserted in the upper arm. In the arm of intervention, participants were given real-time intermittent Continuous Glucose Monitoring for six days during first pregnancy visit at 12, 8, 27, 21 and 33 weeks together with the routine pregnancy care [6]. Continuous use of real-time Continuous Glucose Monitoring was encouraged in women especially those who had hypoglycemia unawareness. Apart from the real-time glucose monitoring, 30 women received other medication. They received antihypertensive treatment. Of the women, 8 were treated with medicine that was antidepressive six of which were serotine selective.

## 2.2. Randomization of Treatment

A program that is computer-generated was employed thus; allocation of treatment was concealed by the help of a phone automated service allocation that was given by the organization. Stratifying of those participating was done with respect to the diabetes type. Arm allocation to the women was done by research personnel who were trained.

# **3. Outcome of Pregnancy Parameters**

The dominance of infants born with a weight is greater than or equal to the 90th centile that was adjusted for the age of gestation which was 31 and predefined sex to be the primary outcome of the study [7]. Neonatal morbidity was reflected using the preterm delivery prevalence *i.e.* more than 37 weeks of gestation and severe hypoglycemia severe neonatal was chosen as the combined secondary end point before the study other outcomes of pregnancy were defined as; miscarriage which is that which occurred 22 weeks or before, SD score birth weight (*z*-score), hypoglycemia neonatal that shows 2-h plasma glucose which is less than 2.5 mmol/L and then malformation congenital which is an abnormality that requires surgery or permanent injury that results afterward [8].

## **Sample Size**

Basing on the 50% prevalence assumption for the infants with large gestational age in the population of study as well as the assumption that usage of real-time Continuous Glucose Monitoring would help lower this to 20 percent while the error type 1 of 5% and 20% of type 2 error, each arm required 45 patients. The study thus intended to be able to do an analysis of the predefined secondary and primary parameter outcome of the ladies who received the intervention against the subject control in the study population entirely.

# 4. Statistical Analysis

Comparison of the women characteristics was done using the Fisher's exact test *i.e.* the chi-square test whenever appropriate for variables that are categorized and the t-test or the Mann-Whitney test when it is appropriate for the continuous variables.

# 4.1. Result

Women who had type one diabetes were 123 while those who had type two diabetes were 31. The self-monitored measurements of plasma glucose were documented for 7 times a day in relation to each and every study visit in the two arms. This is presented in **Table 1**. The real-time Continuous Glucose Monitoring was started at just the first visit of pregnancy in all the 79 women allocated to be intervened and which was without much side effects generally. Sixty-four percent women with either of the two diabetes types used the real-time Continuous Glucose Monitoring per each protocol. A nearly continuous real-time Continuous Glucose Monitoring use was chosen by only 7% of the women see **Figure 1**.

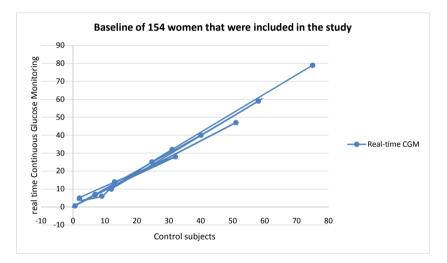
# 4.2. Glycemic Control

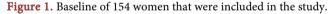
The self-monitored glucose values of plasma, as well as plasma glucose biochemical profiles of the hyperglycemia were same throughout pregnancy in women who used the real-time Continuous Glucose Monitoring in comparison with the subject controls for the population entirely of study [7]. The results of the glycemic control have been presented in **Table 2**. The results revealed that 16% of women that experienced severe hypoglycemia see **Figure 2**.

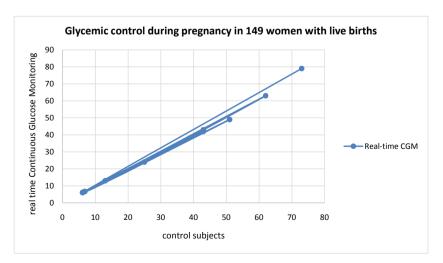
#### 4.3. Pregnancy Outcome and Complications

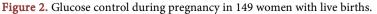
Of the 154 pregnancies, 5 resulted in miscarriages while 149 were births that were live. In both arms, large for gestational age infants were the same in the two arms and there was no difference between the secondary outcomes that were predefined. The same results were recorded in the women who had type one diabetes [8].

Congenital malfunctions happened in two infants. These were from women who had type one diabetes. A single occurrence of death that was prenatal occurred for a short time after the delivery of the infant by a woman who had type two diabetes as a result for severe dystocia of the shoulders. The results are shown in **Table 3** and **Figure 3**.









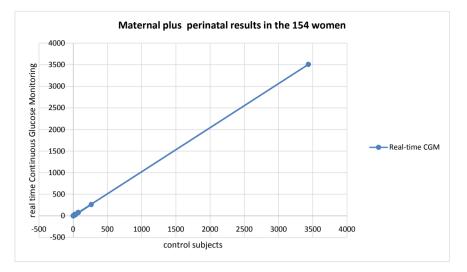


Figure 3. Maternal plus perinatal results in the 145 women.

	Real-Time Continuous Glucose Monitoring	Control Subjects	p-Value
N	79	75	
Age of mothers in years	31	31	0.88
Pregestational BMI in kg/m <sup>3</sup>	25.1	24.7	0.69
Duration of diabetes in years	10	12	0.38
Gestational age in days	59	58	0.61
Nulliparous	40	40	0.74
HbA <sub>1c</sub> in %	6.6	6.8	0.67
HbA <sub>1c</sub> in mmol/mol	47	51	-
Insulin dose in IU/kg/24h	0.60	0.61	0.20
SMPG per day measurement	7	7	0.49
Retinopathy diabetic	28	32	0.29
Elevated urine albumin excretion	5	2	0.44
Smoker	6	9	0.33
Hypoglycemia that was severe in the expectancy preceding year	14	13	0.95

Table 1. Baseline of 154 womer	that were included in the study.
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 Table 2. Glycemic control during pregnancy in 149 women with live births.

	Real-Time Continuous Glucose Monitoring	Control Subjects	p-Value
Ν	79	73	-
8 weeks in percentage	6.6	6.8	0.72
8 weeks in mmol/mol	49	51	-
33 weeks in %	6.1	6.1	0.39

#### Continued

Continued			
33 weeks in mmol/mol	43	43	-
36 weeks in %	6.0	6.1	0.63
36 weeks in mmol/mol	42	43	-
8 weeks	6.7	6.8	0.31
33 weeks	6.2	6.2	0.64
Less than or equal to 3.9 mmol/mol	13	13	0.95
4.0 - 7.9 mmol/mol	63	62	0.57
Greater than 8.0 mmol/mol	24	25	0.38

	1	able 3.	Maternal	plus perinat	al results in the	154 women.
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	Real-Time Continuous Glucose Monitoring	Control Subjects	p-Value
Ν	79	73	-
Number of live births	75	73	-
Number of miscarriages	2	2	1.00
Males	34	31	0.77
Weight gained in expectancy in kg	14.3	13.9	0.92
Preeclampsia	7	6	0.83
Caesarian section	28	33	0.29
Age of gestation at birth in days	264	264	0.14
Preterm delivery	16	12	0.47
Birth weight in g	3,510	3,436	0.80
Birth weight z score	1.07	0.66	0.20
Large for gestational age infant	34	25	0.19
2-h glucose in plasma in mmol/mol	2.8	2.8	0.22
Neonatal hypoglycemia	25	29	0.62
Severe neonatal hypoglycemia	9	10	0.88

# **5.** Conclusion

The results of the study are in conjunction with the intermittent real-time Continuous Glucose Monitoring on a scheduled basis in a women population which was not selected that have pregestational diabetes and who are already carrying out plasma glucose that is self-monitored which measured for about seven times in a day by introducing the real-time Continuous Glucose Monitoring. The findings of study that were negative lead to focus that are intensified on the dietary advice, stable intake of carbohydrates day to day more so in late gestation as well as gaining of weight within an institute of medicine recommendations. Introduction of the real-time Continuous Glucose Monitoring seems to be an efficient way of reducing the rate of severe hypoglycemia in expectant women.

# **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

## References

- Nielsen, R.L., Damm, P. and Mathiesen, E. (2016) Improved Pregnancy Outcome in Type 1 Diabetic Women with Microalbuminuria or Diabetic Nephropathy: Effect of Intensified Antihypertensive Therapy? *Diabetes Care*, **32**, 38-44. https://doi.org/10.2337/dc08-1526
- [2] Vestgaard, M., Ringholm, L., Laugesen, C., Rasmussen, K., Damm, P. and Mathiesen, E. (2016) Pregnancy-Induced Sight-Threatening Diabetic Retinopathy in Women with Type 1 Diabetes. *Diabetic Medicine*, 27, 431-435. https://doi.org/10.1111/j.1464-5491.2010.02958.x
- [3] Secher, A., Stage, E., Ringholm, L., Barfred, C., Damm, P. and Mathiesen, E. (2017) Real-Time Continuous Glucose Monitoring as a Tool to Prevent Severe Hypoglycaemia in Selected Pregnant Women with Type 1 Diabetes—An Observational Study. *Diabetic Medicine*, **31**, 352-356. <u>https://doi.org/10.1111/dme.12383</u>
- Secher, A., Madsen, A., Ringholm, L., Barfred, C., Stage, E. and Andersen, H., *et al.* (2015) Patient Satisfaction and Barriers to Initiating Real-Time Continuous Glucose Monitoring in Early Pregnancy in Women with Diabetes. *Diabetic Medicine*, 29, 272-277. <u>https://doi.org/10.1111/j.1464-5491.2011.03426.x</u>
- [5] We, J., Park, I., Jang, D., Choi, S., Lee, G. and Shin, J. (2016) Optimal Gestational Age of Delivery to Decrease Neonatal Morbidity in Preterm Pregnancies in Korea. *Journal of Obstetrics and Gynaecology Research*, **37**, 563-570. https://doi.org/10.1111/j.1447-0756.2010.01398.x
- Secher, A., Schmidt, S., Nørgaard, K. and Mathiesen, E. (2016) Continuous Glucose Monitoring-Enabled Insulin-Pump Therapy in Diabetic Pregnancy. *Acta Obstetricia et Gynecologica Scandinavica*, 89, 1233-1237. https://doi.org/10.3109/00016349.2010.498499
- [7] Nielsen, L., Pedersen-Bjergaard, U., Thorsteinsson, B., Johansen, M., Damm, P. and Mathiesen, E. (2016) Hypoglycemia in Pregnant Women with Type 1 Diabetes: Predictors and Role of Metabolic Control. *Diabetes Care*, **31**, 9-14. https://doi.org/10.2337/dc07-1066
- [8] Clausen, T., Mathiesen, E., Ekbom, P., Hellmuth, E., Mandrup-Poulsen, T. and Damm, P. (2018) Poor Pregnancy Outcome in Women with Type 2 Diabetes. *Diabetes Care*, 28, 323-328. <u>https://doi.org/10.2337/diacare.28.2.323</u>