

## Gestational diabetes and macrosomia among Greenlanders. Time to change diagnostic strategy?

Michael Lyng Pedersen<sup>a,b</sup>, Ole Lind<sup>c</sup>, Trine Abelsen<sup>a</sup>, Jesper Olesen<sup>a</sup> and Marit Eika Jørgensen<sup>b,d</sup>

<sup>a</sup>Queen Ingrid Primary Health Care Center, Nuuk, Greenland; <sup>b</sup>Greenland Center of Health Research, Institute of Nursing and Health Science, University of Greenland, Nuuk, Greenland; <sup>c</sup>Department of Gynaecology and Obstetrics, Queen Ingrid Hospital, Nuuk, Greenland; <sup>d</sup>Steno Diabetes Center Copenhagen, Gentofte, Denmark

### ABSTRACT

Gestational diabetes mellitus (GDM) is a serious condition associated to both maternal and offspring complications. Yet, no globally accepted consensus exists on how to test and diagnose GDM. In Greenland, the clinical criteria for testing and diagnosing GDM are adapted from Danish guidelines. The aim of this study was to estimate the prevalence of GDM among Greenlanders using both the current clinical GDM criteria and the recent WHO 2013 criteria and, further, to study the association between GDM, pre-pregnant overweight or obesity and macrosomia. A cross-sectional study of all 450 Greenlandic women who gave birth to a singleton in Nuuk within 1 year was performed. Based on an oral glucose tolerance test measuring capillary whole blood glucose, 119 women were categorised as having clinical GDM, WHO 2013 GDM or not GDM. Macrosomia defined as birth weight above 4,000 g was used as outcome variable. The prevalence of clinical GDM and WHO 2013 GDM was 0.4% (95% CI; 0–1.1) and 6.9% (95% CI; 4.5–9.2). WHO 2013 GDM, fasting blood glucose, pre-pregnant maternal overweight and obesity were associated with macrosomia. WHO 2013 GDM criteria were superior to clinical criteria in predicting macrosomia indicating that it may be time to consider the diagnostic strategy used in Greenland. Pre-pregnant overweight may also need more intensified lifestyle-intervention.

**Abbreviations:** GDM: Gestational diabetes mellitus; VP: venous plasma; CWB: capillary whole blood; OGTT: oral glucose tolerance test; WHO: World Health Organisation; FIGO: The International Federation of Gynaecology and Obstetrics; BMI: body mass index; GA: gestational age

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### Introduction

Gestational diabetes mellitus (GDM) is defined as hyperglycaemia diagnosed during pregnancy [1]. GDM is associated with maternal and offspring complications like macrosomia, caesarean delivery, preterm birth, intrauterine death, preeclampsia, shoulder dystocia, neonatal hypoglycaemia and hyperbilirubinaemia [2,3]. Women diagnosed with GDM have an increased risk at around 50% of developing diabetes later in life [4,5]. Also, offspring of mothers with GDM have increased risk of obesity and diabetes later in life [6,7]. Globally, the prevalence of GDM has increased within the last 20 years [8,9]. The first study of GDM performed in Greenland reported a very low prevalence of GDM among women from Nuuk who gave birth in 2008 [10]. However, only 54% of eligible women was actually tested with an oral glucose tolerance test (OGTT) for GDM [10]. A later study including all women who gave birth to a singleton in all Greenland 2014 reported a

higher testing rate at 85% in Nuuk indicating improved testing rate in Nuuk compared to 2008 [11]. The prevalence among Greenlanders was still reported low. However, the authors also concluded that GDM may be under-diagnosed because testing for GDM in Greenland was risk factor based rather than universal, and because only 2-h blood glucose was included and not fasting nor 1-h blood glucose. Yet, no globally accepted consensus on how to test and diagnose GDM exists. Also, the possibility to use capillary blood glucose in resource-constrained areas instead of venous plasma has been intensely debated [12,13]. In Greenland, the testing criteria and use of 2-h blood glucose values follow the guidelines used in Denmark published by the Danish Society of Obstetrics and Gynaecology in 2014 [14] based on any 1 of the following criteria: overweight (pre-pregnant body mass index [BMI]  $\geq 27$  kg/m<sup>2</sup>), glucosuria, family history of diabetes among first-degree relatives or grandparents, previous delivery of an infant with a birth weight  $\geq 4,500$  g and

GDM during earlier pregnancies. Testing is performed using a 75-g OGTT at 28 gestational weeks. In addition, an OGTT is performed at 18 gestational weeks if more than 1 risk factor is present or if GDM was observed in a former pregnancy. Diagnosis of GDM in Greenland is based on capillary whole blood glucose (CBG) concentration examined 2 h after the administration of glucose. A value at 9.0 mmol/l or above is considered diagnostic for GDM. The diagnostic cut-off used in Greenland is thus higher than the International Association of Diabetes and Pregnancy Groups recommendations for diagnosis of GDM based on fasting venous plasma glucose (VPG) at or above 5.1 mmol/l, 1 h VPG at or above 10.0 mmol/l or 2-h VPG at or above of 8.5 mmol/l [15]. Identical criteria have also been adapted by the World Health Organisation (WHO) in 2013 [16]. Thus, the prevalence of gestational diabetes in Greenland using the new WHO 2013 criteria remains unreported. In addition, no associations with GDM, pre-pregnant overweight or pre-pregnant obesity among Greenlanders and adverse birth outcomes have been estimated. The aim of this study was to estimate the prevalence of GDM among Greenlanders using both the current clinical GDM criteria and the more recent WHO 2013 criteria and, further, to study the association between GDM according to the different diagnostic criteria, pre-pregnant overweight or obesity and macrosomia.

## Methods

This study was performed as an observational cross-sectional study based on information in the electronic medical record (EMR).

The capital of Greenland, Nuuk, has around 17,000 inhabitants corresponding to almost a third of the entire population of Greenland. Prenatal care for pregnant women in Nuuk including first prenatal care visit is performed by midwives working at Queen Ingrid Hospital where the only department of obstetrics in Greenland is located. Outside Nuuk, prenatal care is performed by midwives in some larger towns. In settlements and towns without midwives, prenatal care is performed by other healthcare professionals, by visiting midwives or the pregnant women visiting towns with midwives [11]. Pregnant women experiencing or at risk of complications during pregnancy are referred to Nuuk for delivery. The remaining births take place locally at hospitals in the larger towns. Women diagnosed with GDM are offered lifestyle intervention including dietary and exercise counselling, monitoring of blood glucose using Freestyle Lite® (Abbott Laboratories A/S, Copenhagen, DK) and

exercise using pedometers and insulin if indicated. The OGTT is performed in fasting, pregnant women with the administration of 75 g pure glucose diluted in water at the central laboratory at Queen Ingrid Hospital. CBG concentration is examined before and 2 h after the administration for glucose using a portable Hemocue Glucose 201® System (AB, Angelholm, Sweden), which is calibrated weekly [11].

All Greenlandic women with permanent address in Greenland and a singleton pregnancy who gave birth in Nuuk from 1 September 2015 to 31 August 2016 were included in the study. Only women born in Greenland were considered Greenlanders and included. Women with pre-gestational diabetes and women treated with oral steroids were not included in the study. Women with 2-h CWB glucose  $\geq 9.0$  mmol/l were considered having clinical GDM according to the present cut-off values for GDM used in Greenland [11]. Women with fasting CWB glucose  $\geq 5.1$  mmol/l or 2-h CWB glucose  $\geq 8.5$  mmol/l were categorised as having WHO 2013 GDM although these cut-off values were based on venous plasma and not CWB. The prevalence of GDM was calculated as the proportion of women with GDM among all women included since testing for GDM was risk factor based.

Baseline variables were included based on information from the EMR. Pre-pregnant BMI was based on the subject's self-reported weight and height before pregnancy. Women with a pre-pregnant BMI between 25 and 30 kg/m<sup>2</sup> were considered overweight while women with a pre-pregnant BMI at or above 30 kg/m<sup>2</sup> were considered obese. The women were categorised as smokers if they reported any tobacco smoking at the first prenatal visit and as alcohol users if any alcohol use was reported at the first prenatal visit. Delivery was considered vaginal unless a caesarean section had been performed. Women without a previous child birth were classified as nulliparous. GA was based on the subject's self-reported last menstrual period. In cases where last menstrual period was unknown and in cases where an ultrasound-based GA calculation deviated 2 weeks or more from the LPM-based GA, the ultrasound-based GA was used [11]. Macrosomia was defined as birth weight above 4,000 g [17], while a birth weight above 4,500 g was considered severe macrosomia [18]. If the delivery was the first by caesarean, it was defined as primary [19]. Preterm delivery was defined as delivery prior to 37 weeks' gestation (259 days' gestation) [19].

Variables were described using medians and inter-quartile range. Associations between different OGTT outcomes and macrosomia were assessed by logistic regression. Confidence interval of 95% was used in

this study. A two-sided p-value below 0.05 was used as the level of significance. Statistical analyses were performed using SPSS statistical software, version 23.0 (Norusis; SPSS Inc., Chicago, IL).

The study was approved by The Ethics Committee for Medical Research in Greenland and the Agency of Health and Prevention in Greenland.

## Results

A total of 450 women were included in the study. Basic characteristics and perinatal and outcomes are listed in Table 1. A total of 119 women (26.4%) were tested for GDM during pregnancy. The prevalence of clinical GDM according to current guidelines was 0.4% (95% CI; 0–1.1). In contrast, WHO 2013 GDM was observed in 31 women corresponding to a prevalence of 6.9% (95% CI; 4.5–9.2). Almost all, 30 out of 31, of the women diagnosed with WHO 2013 GDM had fasting CWB glucose at or above 5.1 mmol/l. Macrosomia was observed in 24.7% (111/449, 1 birth weight was missing) of the all the included cases. The proportion of pregnant women with macrosomia categorised by selected OGTT outcomes or pre-pregnant overweight or obesity is illustrated in Table 2. The highest proportion of macrosomia (61.3%), positive predictive value, was observed among women diagnosed with WHO 2013 GDM followed by an almost identical group of women with fasting CWB glucose at or above 5.1 mmol/l (60.0%), and 50% among those with clinical GDM. The proportion of macrosomia, around one-third, was

**Table 1.** Basic characteristics of women included in the study.

Variable	N = 450 Median (IQR) or % (n)
Maternal age (years)	27.0 (9)
Height (cm)	162 (8)
Weight before pregnancy (kg)	66 (20)
BMI before pregnancy (kg/m <sup>2</sup> )*	24.9 (7.5)
Maternal BMI ≥25 kg/m <sup>2</sup> , % (n)*	49.9 (197)
Maternal BMI ≥30 kg/m <sup>2</sup> , % (n)*	23.5 (93)
Smoking during pregnancy, % (n)	44.4 (200)
Alcohol during pregnancy, % (n)	1.1 (5)
Nulliparous, % (n)	36.9 (166)
OGTT performed, % (n)	26.4 (119)
Clinical GDM, % (n)	0.4 (2)
2H-CWBG ≥9.0mmol/l	
WHO 2013 GDM, % (n)	6.8 (31)
F-CWBG ≥5.1 or 2H-CWBG ≥8.5 mmol/l	
F-CWBG ≥5.1 mmol/l, % (n)	6.6 (30)
<b>Perinatal outcome</b>	
Gestational age at delivery (days)	276 (15)
Vaginal delivery, % (n)	88.4 (398)
Primary caesarean, % (n)	6.4 (29)
Male offspring, % (n)	54.9 (247)
Macrosomia >4,000 g, % (n)**	24.7 (111)
Severe macrosomia >4,500 g, % (n)**	4.7 (21)
Preterm birth, % (n)	8.2 (37)

\*N = 395, \*\*N = 449. F-CWBG: Fasting capillary whole blood glucose; 2H-CWBG: 2-h capillary whole blood glucose.

**Table 2.** Proportion of pregnant women with macrosomia categorised by selected OGTT outcomes or pre-pregnant BMI.

Variable	Macrosomia (birth weight ≥4,000 g)		Logistic regression p
	%	OR [95% CI]	
Clinical GDM 2H-CWBG ≥9.0 mmol/l (n = 2)	50.0	3.1 [0.2–49.4]	0.430
WHO 2013 GDM F-CWBG ≥5.1 mmol/l or 2H-CBG ≥8.5 mmol/l (n = 31)	61.3	5.6 [2.6–12.0]	<b>&lt;0.001</b>
F-CWBG ≥5.1 mmol/l (n = 30)	60.0	5.3 [2.4–11.3]	<b>&lt;0.001</b>
Maternal overweight (BMI ≥ 25) (n = 197)	33.5	2.3 [1.4–3.6]	<b>0.001</b>
Maternal obesity (BMI ≥ 30) (n = 93)	36.6	2.0 [1.2–3.3]	<b>0.007</b>

F-CWBG: Fasting capillary whole blood glucose; 2H-CWBG: 2-h capillary whole blood glucose.

p-values below 0.05 are in bold.

almost similar among women with pre-pregnancy obesity and pre-pregnant overweight indicating that overweight is a risk factor for macrosomia among Greenlanders. WHO 2013 GDM, fasting CWB glucose above 5.1 mmol/l, pre-pregnant maternal overweight and obesity were significantly associated with increased risk of macrosomia (see Table 2). The association for both fasting CWB glucose above 5.1 mmol/l (p = 0.003) and WHO 2013 GDM (p = 0.001) remained significant after adjusting for pre-pregnant overweight, parity and maternal age. The association between overweight (p = 0.005) and obesity (p = 0.003) remained significant after adjusting for smoking during pregnancy, infant gender, maternal age and parity. Sensitivity, specificity, agreement, positive and negative predictive values for macrosomia categorised by selected OGTT outcomes or pre-pregnant overweight and obesity are illustrated in Table 3. The sensitivity of clinical GDM, 2.2%, was much lower than 41.3% observed for WHO 2013 GDM, while the specificity was 98.6% and 83.6%, respectively. The sensitivity based on overweight was higher than any of the GDM criteria (64.7%). However, the corresponding specificity was much lower (55.3%).

## Discussion

The prevalence of clinical GDM (0.4%) was very low compared to the prevalence of WHO 2013 GDM at 6.8%. WHO 2013 GDM, fasting CBG above 5.1 mmol/l, pre-pregnant maternal overweight and obesity were significantly associated with increased risk of macrosomia.

The highest sensitivity with acceptable specificity was observed for WHO 2013 GDM criteria.

The present study is the first to study the association between GDM and adverse outcomes among

**Table 3.** Sensitivity, specificity, agreement, positive and negative predictive values for macrosomia categorised by selected OGTT outcomes or pre-pregnant BMI.

Variable	Macrosomia (birth weight $\geq 4,000$ g)				Agreement % (95% CI)
	Sensitivity % (95% CI)	Specificity % (95% CI)	Positive PV % (95% CI)	Negative PV % (95% CI)	
Clinical GDM 2H-CWH $\geq 9.0$ mmol/l (n = 2)	2.2 (0–6.4)	98.6 (96.0–101.3)	50.0 (0–59.1)	61.3 (52.6–70.1)	61.3 (52.6–70.1)
WHO 2013 GDM F-CWBG $\geq 5.1$ mmol/l or 2H-CWBG $\geq 8.5$ mmol/l (n = 31)	41.3 (27.1–55.5)	83.6 (75.1–92.1)	61.3 (44.1–71.5)	69.3 (59.7–79.0)	67.2 (58.8–75.7)
F-CWBG $\geq 5.1$ mmol/l (n = 30)	39.1 (25.0–53.2)	83.6 (75.1–92.1)	60.0 (42.5–70.2)	68.5 (58.9–78.2)	66.4 (57.9–74.9)
Maternal overweight (BMI $\geq 25$ ) (n = 197)	64.7 (55.4–74.0)	55.3 (49.6–61.0)	33.5 (26.9–40.1)	81.8 (76.4–87.2)	57.7 (52.8–62.6)
Maternal obesity (BMI $\geq 30$ ) (n = 93)	33.3 (24.2–42.5)	79.9 (75.3–84.5)	36.6 (26.8–42.0)	77.5 (72.8–82.5)	67.8 (63.2–72.5)

F-CWBG: Fasting capillary whole blood glucose; 2H-CWBG: 2-h capillary whole blood glucose.

Greenlanders. However, several limitations exist and the results must be taken with reservations. The number of GDM and adverse outcome is still small. Thus, only macrosomia was included in the statistical analysis. Also, only CWB glucose values were included in this study because VPG measurement is not used in Greenland. However, since the practical management of OGTT and GDM in Greenland is based on CWB glucose values, observations on these may be relevant in the consideration of using another strategy. Also, it has been reported that in settings where VPG estimations are not possible, CWB glucose measurements can be used as a screening test for GDM, using lower 2-h CWB glucose cut points to maximise the sensitivity [12,13]. This point of view is supported by The International Federation of Gynaecology and Obstetrics (FIGO) publication from 2015 [20]. It was stated that plasma calibrated handheld glucometers is acceptable to use for the diagnosis of glucose intolerance in pregnancy in locations where laboratory support is either unavailable or at a site remote to the point of care [20]. The prevalence of WHO 2013 GDM at 6.8% reported in this study is the highest prevalence of GDM reported in Greenland until now [10]. This may be a result of the increasing prevalence of overweight and obesity observed among Greenlandic women within the last 2 decades [21]. Increasing prevalence of GDM among Greenlanders is expected to lead to increasing prevalence of macrosomia. Within the last 25 years, the average birth weight in Greenland has increased from 3420 g in 1990 to 3621 g in 2014 according to the annual reports from Chief Medical Officer in Greenland [21]. Since higher birth weight is associated to increased risk of adult obesity among Greenlanders [22], a vicious circle leading to even higher prevalence of overweight and obesity in future Greenlandic generations is a worrying scenario. Combined lifestyle interventions including education, diet, exercise and self-monitoring of blood glucose

with or without pharmacotherapy among women with GDM is associated with lower incidence of macrosomia and other adverse outcomes [23]. Thus, increased focus on diagnosing and treating of GDM in Greenland may have both short and long-term preventive effects.

The highest sensitivity (41.3%) with acceptable specificity was observed for WHO GDM 2013 criteria. Still, the sensitivity for macrosomia is quite low underlining that macrosomia is associated to other factors than GDM too. Actually, a higher sensitivity was observed for pre-pregnant overweight but with a corresponding lower specificity. However, also, other calculations than sensitivity or specificity have to be included in considerations of diagnostic strategy.

Replacing the actual use of 2-h CWB glucose at or above 9.0 mmol/l with the WHO 2013 GDM diagnostic criteria would result in a 15-fold prevalence of GDM in Greenland. Still, the absolute number of patients would be limited. With approximately 800 pregnancies annually in Greenland, the absolute number of women with GDM would increase from 4 (0.4%) to 54 (6.8%). Furthermore, most of women diagnosed with GDM could be treated with lifestyle intervention only. A recent study from United Kingdom reported a prevalence of GDM at 3.7% using the former WHO1999 criteria compared to 11.4% using the new criteria used in United Kingdom (2015 NICE) and 13.7% using WHO 2013 criteria. The significant number of additional cases was detected when using the more recent criteria represented an intermediate group with “moderate” dysglycaemia [24].

Also, universal screening compared to risk factor-based screening would affect the prevalence of diagnosed GDM. Thus, changing testing strategy among Aboriginals in Australia from selective risk-factor-based screening to universal screening resulted in an increase of 40% in prevalence of GDM [25]. Actually, FIGO recommends that all pregnant women are tested for GDM using a 1-step procedure [20]. However, choosing diagnostic cut-off and testing

strategy in Greenland have to be a balanced decision including both possible health effects on pregnancy outcome, capacity of treatment within the health care system and inducing feeling of being sick among pregnant women. Indeed, management should be in accordance with available national resources and infrastructure even if the specific diagnostic and treatment protocols are not supported by high-quality evidence according to FIGO recommendations [20]. Women diagnosed with GDM in Greenland have to deliver in Queen Ingrid Hospital in Nuuk, and for women living outside Nuuk, this means away from family and other children at least a month prior to expected delivery. However, testing pregnant women with the cumbersome OGTT without reacting on elevated fasting CBG values seems problematic taking into account the observed association between fasting CBG and macrosomia in the present study.

In conclusion, the prevalence of clinical GDM was very low compared to prevalence of WHO 2013 GDM among Greenlanders. The WHO 2013 GDM criteria were clearly superior to the current used criteria in predicting macrosomia indicating that it may be time to consider the diagnostic strategy of GDM in Greenland. Furthermore, the strong association between maternal pre-pregnant overweight and macrosomia indicates that lifestyle intervention is highly relevant in this group. Thus, intensified lifestyle intervention early in pregnancy could be included in the consideration of a new model of managing pre-pregnant overweight and GDM in Greenland.

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