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Seremban Cohort Study (SECOST): a prospective study of determinants and pregnancy outcomes of maternal glycaemia in Malaysia

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ABSTRACT

Introduction Both gestational diabetes mellitus (GDM) and hyperglycaemia less severe than GDM are associated with risk of adverse pregnancy outcomes. We describe the study design of a prospective cohort of pregnant women recruited in early pregnancy with follow-ups of mothers and infants up to 2 years after birth. The primary aim of the study was to identify the determinants and outcomes of maternal glycaemia.

Methods and analysis Seremban Cohort Study (SECOST) is an ongoing prospective cohort study in which eligible pregnant women in first trimester (<10 weeks of gestation) are recruited from Maternal and Child Health clinics in Seremban District, Negeri Sembilan with seven follow-ups during pregnancy through 2 years postnatally. Infants are followed up every 6 months after birth until 2 years old. A standard 75 g oral glucose tolerance test is performed between 24 and 32 of weeks of gestation and as close to 28 weeks of gestation. Pregnancy and birth information are obtained from medical records. Sociodemographic, anthropometric, biochemical, dietary, physical activity, smoking, depression, child feeding and other data of mothers and infants are obtained at follow-ups.

Ethics and dissemination This study is approved by the Medical Research Ethics Committee (MREC), Universiti Putra Malaysia (UPM/FPSK/100-9/2-MJKEtika) and MREC, Ministry of Health Malaysia (KKM/NIHSEC/08/0804/P12-613). Permission to conduct this study is also obtained from the Head of Seremban District Health Office. All participants are required to provide written informed consent prior to data collection. The research findings will be disseminated at journals and conference presentations.

Strengths and limitations of this study

- SECOST (Sremban Cohort Study) is the first prospective study in Malaysia to provide data on determinants and pregnancy outcomes of maternal glycaemia.
- Information on lifestyle factors and weight gain patterns during pregnancy will provide insight on determinants of maternal glycaemia.
- Data on birth and early child growth patterns will inform on the short-term and long-term outcomes of maternal glycaemia.
- The cohort of pregnant women and their offsprings may not represent the general population of pregnant women and infants in Malaysia due to the location of subject recruitment and study selection criteria.
- High attrition rate of subjects during pregnancy and infancy is expected.

INTRODUCTION

During pregnancy, substantial changes occur in glucose, lipid and protein metabolism as to meet the increasing demands of the fetus. In a normal pregnancy, an increase in insulin resistance will reduce glucose uptake into maternal tissues as to make glucose more readily available for fetal growth. This hyperglycaemic state is mainly due to the increased production of placental growth hormones that may interfere with insulin receptor's action and inhibit glucose uptake as pregnancy progresses.[1] Pregnant women will develop elevated blood glucose level (hyperglycaemia) or gestational diabetes mellitus (GDM) if the mother's beta cells are unable to increase insulin secretion to compensate for the insulin resistance in pregnancy.

The international multicenter Hyperglycemia and Adverse Pregnancy Outcomes study reported that maternal fasting and stimulated glucose levels showed linear associations with risks of increased size at birth, caesarian delivery, neonatal hypoglycaemia and fetal hyperinsulinaemia.[2] On the basis of this landmark study, the International Association of Diabetes in Pregnancy Study Groups and the American Diabetes Association have recommended new lower diagnostic criteria for GDM.[3] However, the use of these new criteria has resulted in a dramatic increase in the number of women diagnosed with GDM.[4–6] Increased healthcare cost and lack

of improvement in maternal and infant outcomes are other concerns related to the new diagnostic criteria.[7] Thus, the optimal diagnostic threshold of GDM during pregnancy remains controversial.

Globally, the prevalence of GDM ranging from 1% to 14% of all pregnancies, depends on the population and diagnostic criteria of GDM.[6] In the USA, GDM affected 7% of all pregnancies annually.[8] In Europe, a 2%–6% prevalence of GDM was reported with a lower prevalence in the Northern Europe (<4%) than in the Southern Europe (>6%).[9] Similarly, in Asian countries, the prevalence of GDM in China,[10] Korea[11] and Thailand[12] were 6.8%, 2%–5% and 5.7%, respectively. GDM rate in Malaysia (8%–11%)[13 14] is much higher than those reported for most Asian populations (2%–7%).[10–12] As the rate of obesity increases among women, a parallel rise in GDM rate is inevitable. The National Health and Morbidity Survey (NHMS) reported that the prevalence of obesity in Malaysian women aged ≥18 years old increased from 5.7% in 1996 to 17.6% in 2011.[15 16] As more women in reproductive age become overweight or obese prior to pregnancy, they will be at greater risk of maternal hyperglycaemia.

At present, limited data are available on determinants and outcomes of hyperglycaemia during pregnancy in Malaysia.[14 17] This study will provide important insights on lifestyle factors and weight gain patterns during pregnancy as determinants as well as birth and early child growth data as short-term and long-term outcomes of maternal glycaemia. In light of increasing rates of child and adult obesity, GDM and diabetes mellitus and persistence of child undernutrition in Malaysia, such information on intergenerational transmission of risk of obesity and non-communicable diseases are pertinent for planning effective strategies that best meet the needs and resources to achieve a future healthy generation.

MATERIALS AND METHODS

Study design

SECOST is an ongoing prospective cohort study in which pregnant women and their infants are followed up through 2 years postnatally. Women in the first trimester (<10 weeks of gestation) of pregnancy are recruited from three[4] Maternal and Child Health (MCH) clinics in Seremban District, Negeri Sembilan, Malaysia. There are seven follow-up visits for mothers (three pregnancy and four postnatal visits) and four follow-up visits for infants at an interval of 6 months after birth (table 1).

Participants

Pregnant women attending MCH clinics for antenatal booking are eligible to participate in the study on screening based on study criteria.

Inclusion criteria

Malaysian women (age >18 years) with singleton pregnancy, body mass index (BMI) ≥18.5 kg/m^2 to <40.0 kg/m^2, normal glycaemia at study enrolment (fasting plasma glucose (FPG) 3.0–6.0 mmol/L) and free from any medical illness or obstetrics complications.

Exclusion criteria

Women with multiple pregnancies, became pregnant with assistance of advanced reproductive technology, unable to complete oral glucose tolerance test (OGTT) within 24–32 weeks of gestation, pre-existing diabetes mellitus (FPG >7.0 mmol/L), diagnosis of diabetes during this pregnancy, abnormal glycaemia (FPG <3.0 mmol/L or FPG >6.0 mmol/L) at study enrolment, previous diagnosis of diabetes requiring treatment with medication outside of pregnancy, BMI >40.0 kg/m^2, other medical problems (eg, HIV positive, hepatitis B or hepatitis C, hypertension, renal disease, anaemia, thalassaemia) at study enrolment.

Recruitment

Study information leaflet is given to all pregnant women attending the three MCH clinics for antenatal booking by nurses. Pregnant women who meet the selection criteria are invited to participate in the study. Study participation is on a voluntary basis and participants can withdraw from the study at any time during the study period. A study manual that outlines the details of study visits and measurements are given to participants. The period of recruitment is from 2013 to 2016.

Sample size

Sample size is estimated using a statistical formula for a proportion by Scheaffer *et al*.[18] Based on 18.3% of pregnant women in Malaysia had abnormal OGTT,[19] 95% confidence level and 5% probability of missing a true difference, a minimum of 230 pregnant women are required as study participants. To account for an attrition rate of 50%, the sample is increased to a minimum of 345 pregnant women.

Measurements

The schedule of measurements for mothers and infants at study enrolment and follow-up visits are summarised in table 1.

Mothers

Sociodemographics

The sociodemographic information obtained include current age, years of education, ethnicity, marital status, occupation, income, spouse's years of education, spouse's occupation, spouse's income and household income.

Dietary intake

Dietary intake is assessed using 24-hour dietary call for 1 day and Food Frequency Questionnaire (FFQ).

Energy and nutrient intakes

A 24-hour diet recall is used to obtain dietary information. Standard household measuring cups, glasses, bowls and spoons are used to assist respondents to estimate food portion size. Dietary data are analysed using Nutritionist

Table 1 Schedule of measurements

Measurements	Study enrolment As early as possible (<10 weeks)	First visit 10–13 weeks of gestation	Second visit 24–32 weeks of gestation	Third visit 34–38 weeks of gestation	Fourth visit 6 months postpartum	Fifth visit 12 months postpartum	Sixth visit 18 months postpartum	Seventh visit 24 months postpartum
Mother								
Sociodemographic	x							
Obstetrical information	x							
Anthropometric measurements								
Waist	x				x	x	x	x
Height	x							
Weight	x	x	x	x	x	x	x	x
Blood pressure	x	x	x	x	x	x	x	x
Biochemical								
Haemoglobin	x	x	x	x				
Fasting glucose	x				x			
Lipid profile	x				x			
Vitamin D	x				x			
OGTT			x					
Dietary intake								
FFQ	x	x	x	x				
24 dietary recall	x	x	x	x	x			
Physical activity	x	x	x	x	x			
Smoking		x						
Food insecurity			x					
Depression				x	x			
Birth information					x			
Infant								
Anthropometric measurements								
Weight					x	x	x	x
Length					x	x	x	x
Head circumference					x	x	x	x
Waist circumference					x	x	x	x
Skinfold thickness					x	x	x	x
Arm circumference								
Postnatal environment								

Continued

Table 1 Continued

Measurements	Study enrolment	First visit	Second visit	Third visit	Fourth visit	Fifth visit	Sixth visit	Seventh visit
	As early as possible (<10 weeks)	10–13 weeks of gestation	24–32 weeks of gestation	34–38 weeks of gestation	6 months postpartum	12 months postpartum	18 months postpartum	24 months postpartum
Dietary intake					×	×	×	×
Infant feeding practices					×	×	×	×
Diet diversity					×	×	×	×

FFQ, food frequency questionnaire; OGTT, oral glucose tolerance test.

Pro Diet Analysis software,[20] and comparison of energy and nutrient intakes is made to the Malaysian Recommended Nutrient Intake[21] to determine intake adequacy. Intakes of grains, meat, fish, legumes, fruits, vegetables and dairy product (g/day) are calculated as number of servings and compared with the Malaysian Dietary Guidelines.[22]

Alcohol use

The frequency of drinking alcohol and amount of alcohol (glass) are obtained.

Energy density

Energy density is calculated by dividing each subject's daily energy intakes (in kilocalories) by the reported weight of all foods consumed (in grams).[23]

Dietary pattern

FFQ is used to assess food consumption patterns. There are 12 main food groups with 50 subfood groups which include cereals, meat and meat products, fish and seafood, eggs, fruits, vegetables, legumes and nuts, milk and dairy products, fat and oil, sugar and sugary food and flavouring and beverages.[24] Dietary patterns are determined based on standard procedures.[25 26]

Dietary glycaemic index and glycaemic load

Dietary glycaemic index (GI) and glycaemic load (GL) are calculated from FFQ and 24-hour dietary recall. The GI values will be categorised into low GI: ≤55, medium GI: 56–70 and high GI: >70. The formulae to calculate dietary GI and GL as used are: [27–29]

Dietary GI = (GI value of the food × frequency of servings of the food per day (g) × carbohydrate content of the food (%))/total daily carbohydrate (g).

Dietary GL = (GI value of the food × frequency of servings of the food per day (g) × carbohydrate content of the food (%)).

Physical activity

Pregnancy Physical Activity Questionnaire (PPAQ) is used to determine physical activity of pregnant women.[30] The PPAQ is a semiquantitative questionnaire that requires participants to report the time spent participating in 32 activities including household/care giving (13 activities), occupational (5 activities), sports/exercise (8 activities), transportation (3 activities) and inactivity (3 activities).

Anthropometry

Weight, height and waist circumference are measured at study enrolment (antenatal booking) using standard instrument (SECA digital weighing scale, SECA body metre and SECA measuring tape). Prepregnancy body weight (current pregnancy) and weight at the beginning of first pregnancy are obtained from medical record. Prepregnancy BMI is calculated as prepregnancy weight (kilogram) divided by recommendation of WHO.[31] Interpregnancy weight change is defined as the difference between weight at the beginning of the first and current

pregnancies. Postpartum weight retention is calculated as the absolute difference between weight measured at each of fourth and fifth visit and prepregnancy weight. Total gestational weight gain is defined as the difference between measured weight at last prenatal visit and prepregnancy weight. Rate of weight gain in first, second or third trimester is defined as the average weekly weight gain in that trimester.

Biochemical

A standard 75 g OGTT is performed at two time points. The first OGTT is performed for all participants at 10–13 weeks of gestation. The second OGTT is performed between 24 and 32 weeks of gestation (second visit) and as close to 28 weeks of gestation as possible. A 2 mL fasting venous blood is drawn prior to ingestion of a standard glucose solution. Another 2 mL of venous blood is drawn at 2 hours after ingestion of standard glucose solution. All blood samples are sent for analysis on the same day to determine fasting glucose, 2-hour plasma glucose concentration. Additional blood (3 mL) is obtained for analysis of total cholesterol, HDL-cholesterol, triglycerides and vitamin D. Normal FPG for pregnant women is defined according to the Ministry of Health (MOH) (3.0 mmol/L to <6.0 mmol/L). The cut-off values for serum lipid is according to the National Cholesterol Education Program Adult Treatment Panel III[32] guidelines. Vitamin D cut-offs for severe deficiency, mild deficiency, insufficiency and sufficiency are <25 nmol/L, 25 to <50 nmol/L, 50 to <75 nmol/L and ≥75 nmol/L, respectively.[33]

Blood pressure

Right arm systolic blood pressure and diastolic blood pressure is measured using OMRON SEM-1 Automatic Blood Pressure Monitor by trained nurses.

Smoking habit

The status of smoking, frequency of smoking and number of cigarettes smoked are obtained.

Food insecurity

A 10 items questionnaire is use to assess women food insecurity. All items are rated on a three response point ranging from always, sometimes or never.[34]

Depression

Depression during pregnancy and postpartum depression is assessed using a self-administered 10 question Edinburg Postnatal Depression Scale.[35]

Maternal birth information

Delivery

Mode of birth (normal vaginal birth, assisted breech delivery, instrumental delivery or caesarean section) and gestational age at birth are obtained from medical record. Premature birth is defined as childbirth occurring at less than 37 completed weeks of gestation or 259 days of gestation.[36]

Birth information of infants

Birth data are obtained from medical record. Birth weight is categorised according to the recommendation of Unicef and WHO.[37] SGA is defined as an infant weighing less than 10th percentile of birth weight. An infant with >90th percentile of birth weight was classified as large-for-gestational age (LGA), while an infant with the 10th–90th percentile of birth weight as appropriate-for-gestational age.[38]

Infants

Anthropometry

All infants are measured for weight (to the nearest 0.1 kg), length (to the nearest 0.1 cm), head circumference and mid arm circumference (to the nearest 0.1 cm) using TANITA digital baby weighing scale with recumbent length metre and SECA fibreglass measuring tape, respectively. Infants are measured using standard procedures as described by Gibson.[39] Growth data are analysed using Anthro Plus software that uses WHO growth standard.[40] Five growth indicators (weight-for-age, weight-for-height, height-for-age, head circumference-for-age and BMI-age) will be determined. In order to assess subcutaneous fat, triceps and subscapular are measured using Harpenden Skinfold Caliper and recorded to the nearest 0.1 mm.[41]

Dietary intake

A 24-hour diet recall is used to obtain dietary information of infants from parents/guardians with the aid of standard household measurements. Dietary data are then analysed for adequacy of energy and nutrients[20 21] as well as dietary diversity.[42] Parents are also interviewed on infant feeding practices (eg, milk feeding and complementary feeding).

Data collection

All enumerators are given an intensive briefing and field training before data collection. Study visits are scheduled on the same day of appointments at MCH clinics. A day before each visit, enumerators are required to remind participants of their clinic appointments through telephone calls. During the visits, participants are interviewed or measured for relevant data. For participants who are not able to be interviewed at the clinics, home visits or telephone interviews are carried out by enumerators.

Data analysis

Data will be analysed using IBM SPSS Statistic V.22. Descriptive statistics (mean, SD, median and frequency) will be used to describe the data. Multiple logistic regression will be used to determine the relationship between predictors and maternal glycaemia, as well as the relationship between maternal glycaemia with pregnancy outcomes controlling for confounding variables. Significant level for all statistical analysis will be set at $P<0.05$.

DISCUSSION

Globally, the prevalence of overweight and obesity is increasing among women, particularly during

reproductive years. A study on trends of obesity in the USA showed that the prevalence of obesity (BMI ≥30 kg/m^2) in US women aged 20–39 years increased from 28.4% in 1999 to 34.0% in 2007.[43] In the Malaysian National Health and Morbidity Survey[15] (NHMS II), women showed a significantly higher prevalence of obesity (BMI ≥30 kg/m^2) (17.5%) than man (10.2%). In the period between the NHMS II (1996) and the NHMS (2011), there was an 11.9% increase in the prevalence of obesity (BMI ≥30 kg/m^2) among females aged ≥18 years old. With increasing prevalence of obesity among women of childbearing age, the risk of having higher prepregnancy BMI and excessive gestational weight gain are inevitable.[44 45] These conditions could further increase the risk of pregnant women to have higher blood glucose level and subsequently poor pregnancy outcomes.

Studies have shown that women with hyperglycaemia during pregnancy are at higher risk for poor pregnancy outcomes, such as caesarean delivery, pregnancy induced hypertension and pre-eclampsia.[19 46 47] Apart from that, mothers with hyperglycaemia during pregnancy tend to have LGA infants and infants with asphyxia and hypoglycaemia.[47–49] These conditions can lead to other long-term child health problems such as obesity, type 2 diabetes, cancer and cardiovascular disease in later life. For the mothers with hyperglycaemia, they are at higher risk of developing cardiovascular disease and overt diabetes, mainly type 2 diabetes in later life.[50–52] However, there is no clear threshold above which women are at high risk and below which they are at low risk. Moreover, the impact of maternal hyperglycaemia, which is characterised by value of glucose tolerance intermediate between normal and gestational diabetes on outcomes of pregnancy remains unclear.

Dietary intake and physical activity are important modifiable risk factors for the development of type 2 diabetes, as well as gestational hyperglycaemia. While higher total fat and lower carbohydrate intakes during second trimester of pregnancy were associated with maternal hyperglycaemia,[53] pregnant women in the high quartile of moderate intensity activity and occupational activity during early pregnancy had about 50% decreased risk of abnormal glucose tolerance.[54] A lower energy intake and higher physical activity are known to improve insulin sensitivity and reduce glucose levels, however, there is less information on dietary nutrients intakes, particularly fat types, vitamin D and iron related to maternal hyperglycaemia, as well as the optimal distribution of macronutrient intakes during pregnancy to prevent maternal hyperglycaemia. Therefore, there is a need for a better understanding of the role of lifestyle factors, especially energy and nutrient intakes, physical activity and sedentary behaviour in the development of maternal hyperglycaemia.

SECOST is the first prospective study in Malaysia to provide a better understanding of weight gain and lifestyle patterns from early pregnancy until 1-year postpartum and to quantitate the relationship between maternal glucose levels and pregnancy outcomes. As GDM impacts maternal and fetal health, detailed information on lifestyle factors, biochemical parameters and weight gain patterns during pregnancy can provide insight on determinants of maternal glycaemia. Data on early child growth and development obtained periodically will provide information on short-term and long-term outcomes of maternal glycaemia and indicate the role of environment (eg, infant feeding, diet, parent–infant interaction and home environment) that could potentially impact child growth and development. Despite the modest sample size, this pregnancy cohort study provides an opportunity for many hypotheses related to maternal and infant health and nutrition to be tested or confirmed. SECOST is expected to provide valuable data that can be used for strengthening existing strategies and formulating new strategies that are in accordance with promoting MCH.

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Contributors ZMS conceptualised and designed the study; contributed to the development of study protocol; supervise data collection; read, revised and approved the final draft of manuscript. YHY conceptualised and designed the study, contributed to the development of study protocol, involved in data collection, drafted the manuscript, read and approved the manuscript. ZR and BNMY contributed to the development of study protocol, read and approved the manuscript. FY and LP involved in data collection, read and approved the manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval This study is approved by the Medical Research Ethics Committee (MREC), Universiti Putra Malaysia (UPM/FPSK/100-9/2-MJKEtika) and the Medical Research Ethics Committee (MREC), Ministry of Health Malaysia (KKM/NIHSEC/08/0804/P12-613). Permission to conduct this study is also obtained from the Head of Seremban District Health Office.

Provenance and peer review Not commissioned; externally peer reviewed.

Author note As the nature of this study is more of exploratory and does not involve any testing of company product, the researchers are free to report any findings of this study in future publications.

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