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Compliance with National Institute of Health and Care Excellence risk-based screening for Gestational Diabetes Mellitus in nulliparous women

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ABSTRACT

Objective: To investigate compliance with risk-based screening for Gestational Diabetes Mellitus (GDM) in a nulliparous cohort.

Design: A retrospective analysis of nulliparous women recruited to a prospective cohort, the Screening for Pregnancy Endpoints (SCOPE) study, was performed. Population included 2428 healthy nulliparous women with singleton pregnancies, recruited within Cork, Ireland; and Manchester, Leeds and London, United Kingdom. Compliance with risk factor screening for GDM was assessed in relation to the following risk factors: obesity, family history of diabetes and increased ethnic risk. GDM was diagnosed using an oral Glucose Tolerance Test (GTT) with locally employed diagnostic criteria. Statistical analysis was performed using Statistical Packages for Social Sciences (SPSS V22). Descriptive statistics are presented for the various baseline characteristics using numbers and percentages. Cross tabulation was used to compare relevant groups. When comparing group distributions Chi-square test was used. p-value <0.05 was considered statistically significant.

Results: In the entire cohort of 2432 women, 27% (650 Women) had one or more identifiable risk factors as defined by National Institute of Health and Care Excellence (NICE) for GDM. Of those that had identifiable GDM risk factors according to the NICE guidelines, 395(60.8%) were appropriately screened. 253 (38.9%) had risk factors but were not screened. 261 (14.6%) had no GDM NICE risk factors but were screened with an oral GTT. Women with a risk factor that were screened with a GTT had an 8.9% ($n = 34$) prevalence of GDM. Of those that were screened but did not have a risk factor 7.7% ($n = 20$) were diagnosed with GDM. Overall, 2% (54 women) of the cohort had a diagnosis of GDM. Ethnicity was the risk factor most likely to be missed ($n = 55$, 66.3%). The GTT test was completed within the recommended gestational window (24–28 weeks) 56.6% ($n = 371$) of the time.

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Conclusion: This study highlights poor compliance with risk factor screening for GDM in nulliparous women. Further investigation into the underlying reasons is warranted as well as the implications for pregnancy outcome.
Trial registration number: ACTRN12607000551493.

Introduction

Gestational Diabetes Mellitus (GDM) is defined as glucose intolerance first recognised in pregnancy [1–4]. It is a disease which occurs in the last half of pregnancy and reoccurs in up to 40% of women [5]. GDM is estimated to affect 2–9% of pregnant women [6] but the reported prevalence is influenced by the method of screening and the diagnostic criteria used [4,7–9]. Untreated GDM is associated with significant morbidity including increased risks of gestational hypertension, polyhydramnios, induction of labour, emergency Caesarean section, large for gestational age infant, macrosomia, admission to neonatal intensive care unit, neonatal hypoglycaemia and respiratory distress [10,11]. The Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO) Study demonstrated that the degree of maternal glucose abnormality correlated with the severity of adverse pregnancy outcomes [12]. Women with GDM are also at significantly higher risk (up to 40%) of developing type 2 diabetes later in life [13–15].

GDM can be detected in pregnancy using a blood test to screen for elevated blood glucose concentrations during the antenatal period. There are two suggested types of screening, risk-based and universal. The National Institute of Clinical Excellence (NICE) and the American Diabetes Association (ADA) guidelines recommend risk-based screening [7,16]. However, it is estimated that risk-based screening will miss up to 30% of women with GDM as not all women with GDM have identifiable risk factors [17]. The International Diabetes Federation (IDF), American College Obstetricians and Gynaecologists and the Australasian Diabetes in Pregnancy Society recommend universal screening unless a selective process based on risk is deemed more appropriate [18–20].

The aims of this study were to assess compliance with risk-based screening for GDM in a prospective international cohort of nulliparous women conducted in settings where risk factor-based screening is normal practice. We hypothesised that there is a poor adherence to risk factor screening resulting in reduced diagnosis of GDM and missed opportunity to adequately treat and as a result prevent the adverse outcomes associated with GDM.

Methods

A retrospective analysis of nulliparous women recruited to a prospective cohort, SCOPE (Screening for Pregnancy Endpoints), a multicentre study with the main aim of developing screening tests to predict pre-eclampsia, small for gestational age infants (SGA) and spontaneous preterm birth [21]. The study was conducted in Auckland, New Zealand; Adelaide, Australia; Cork University Maternity Hospital, Cork, Ireland; and Manchester (St. Mary's Hospital, Central Manchester University Hospitals NHS Trust), Leeds (St James' University Hospital, Leeds Teaching Hospitals NHS Trust) and London (St. Thomas' Hospital, Guy's and St. Thomas' NHS Foundation Trust), United Kingdom (UK). For the purpose of this study, we restricted our study to Ireland and UK centres, where risk factor screening is performed. The SCOPE study is described in detail elsewhere [21,22]. In brief, healthy nulliparous women with singleton pregnancies were recruited into the study between May 2007 and February 2011. Women perceived to be at high risk of pre-eclampsia, spontaneous pre-term birth and SGA babies were excluded.

Ethical approval was obtained from local ethics committees [London, Leeds and Manchester 06/MRE01/98 and Cork ECM5(10)05/02/08] and all participants provided written informed consent. Women were interviewed at 15 [14–16] weeks' gestation and at 20 [19–21] weeks' gestation. At 15 weeks' gestation an in-depth history was taken by a research midwife. This included the recording of risk factors associated with GDM based on NICE guidelines. NICE recommends screening any pregnant women with any one of the following; obesity (BMI $> 30\ kg/m^2$), previous macrosomia ($\geq$4.5 kg), history of GDM, first degree relative with diabetes or Hispanic, African, Native American, South or East Asian, or Pacific Islands ancestry [16]. Previous macrosomia and a history of GDM did not apply to SCOPE cohort as the women were nulliparous. Participants were followed prospectively and pregnancy outcomes recorded. Screening for GDM was not included in the SCOPE protocol and was performed according to relevant local or national guidelines. Data were entered on an internet accessed central database with a complete audit trail (MedSciNet). The focus of this study was to investigate compliance with recommended risk factor screening.

Screening and diagnosis of GDM

All centres utilised risk factor screening based on NICE guidelines with some variations.

In Ireland, the risk factors were identical to those used in the UK centres (NICE guidelines) but also included maternal age over 40 years and diagnosis of PCOS. In Manchester, screening was based on the NICE guidelines with the exception of ethnicity, which was not included in their local guidelines.

Screening was performed using a Glucose Tolerance Test (GTT) based on a 75 mg oral glucose load and a venous whole blood glucose test performed at 24–28 weeks' gestation. However, diagnostic criteria differed between centres. In Manchester, a diagnosis of GDM was made if fasting blood glucose was $\geq$6.0 mmol/L and/or a 2 h post glucose load of $\geq$9.0mmol\L GDM. In Leeds and Cork, the criteria for diagnosis were a fasting blood glucose $\geq$5.5 mmol/L and/or a 2 h post glucose load of $\geq$7.8 mmol\L. In London, a diagnostic test cut off of fasting blood glucose $\geq$5.5 mmol/L and a 2 h post glucose load of $\geq$9 mmol/L was used.

Statistical analysis was performed using Statistical Packages for Social Sciences (SPSS V22). Descriptive statistics are presented for the various baseline characteristics using numbers and percentages. Cross tabulation was used to compare relevant groups. When comparing group distributions, Chi-square test was used. p-value <0.05 was considered statistically significant.

Results

A total of 2432 women were recruited to the participating centres. Data for analysis were available on 2428 (99.9%) of women. Overall, the population were primarily Caucasian ($n = 2287$; 94%), aged between 25 and 35 years ($n = 1828$; 75%; Table 1). Of the 2428 women 650 (26.7%) had identifiable risk