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

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Condensation

This study shows very poor compliance with the use of National Institute of Health and Care Excellence (NICE) guidelines in risk based screening in both Irish and UK settings.

Abstract

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

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% percent (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.

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

Keywords

Gestational diabetes, risk factor, screening, compliance, pregnancy

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, 19) (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, 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 small for gestational age 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 ($BMI > 30 \text{ kg/m}^2$), previous macrosomia ($\geq 4.5 \text{ kg}$), 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 75mg oral glucose load and whole blood glucose tests 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 ≥ 6.0 mmol/L and/or a 2 hour post glucose load of ≥ 9.0 mmol/L. In Leeds and Cork the criteria for diagnosis were a fasting blood glucose ≥ 5.5 mmol/L and/or a 2 hour post glucose load of ≥ 7.8 mmol/L. In London, a diagnostic test cut off of fasting blood glucose ≥ 5.5 mmol/L and a 2 hour post glucose load of ≥ 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 factors according to the NICE guidelines and of these 395 (60.8%) were appropriately screened. 253 (38.9%) women had risk factors but were not screened. 261 (14.6%) had no NICE risk factors but were screened with a GTT. There was an 8.9% prevalence of GDM in women that had a risk factor and were screened. Table 2 demonstrates the breakdown of GDM diagnosis for each centre using their own GTT cut off ranges. Of those that were screened but did not have a risk factor 7.7% (n=20) were diagnosed with GDM. 2% (n=54) of the cohort had a diagnosis of GDM. (Figure 1)

Compliance with screening was less in the UK centres compared to the Irish centre (71% vs 42%). 78% (n=172) of obese women in the Irish cohort were correctly screened compared to 49% (n=39) of the women in the UK centres. 78% (n=159) with family history of diabetes were screened in Irish cohort versus 56% (n=58) in the UK. 42% (n=15) of women with an ethnicity considered to be a risk factor were screened in Ireland versus 23% (n=13) in the UK (Leeds, Manchester and London).

When the compliance with NICE risk factor screening was assessed, ethnicity was the risk factor most likely to be missed. Following exclusion of Manchester participants (where ethnicity was not included as a risk factor) screening was not carried out in 66.3% (n=55) of women from ethnic groups at risk. Only 33% (n=4) of those with Asian ethnicity, 26% (n=9) of African ethnicity and 43% (n=15) of Indian ethnicity had a GTT. In the whole cohort,

obese women ($\text{BMI} \geq 30 \text{ kg/m}^2$) were not screened in 29% (n=88) of cases, Women who reported a first degree family relative with diabetes were not screened in 33% (n=106) of cases.

One person with all three risk factors was not screened with GTT. (Table 3) In the Irish cohort where maternal age over 40 and diagnosis of PCOS were also considered risk factors when screening for GDM, compliance was also poor. Of those women aged 40 or older 77.4% (n=24) were not screened. Of those diagnosed with PCOS, 53.7% (n=51) were not screened.

In the Irish cohort both public and private patients participated in the study (82% public v 18% private). When the service provider was examined, similar deficiencies in screening were observed in both health care settings. Of the women with a NICE risk factor (n=420), 72% of public patients were appropriately screened versus 67% of private patients.

The GDM was diagnosed on a total of 56 women. 50% (n=29) were assessed at 24-28 weeks' gestation as recommended. GTT was performed at 21-23 weeks' gestation in 1.9% (n=1) and at 28-38 weeks' gestation in 48.1% (n=26).

Discussion

Main Findings

This study of nulliparous women demonstrated that compliance with risk based screening for GDM based on NICE guidelines was poor, with 40% of women with a defined pre-pregnancy risk factor not subsequently screened. This finding supports previous studies conducted in Thailand and Sweden which demonstrated a poor compliance rate with risk based

screening.(23) However, unlike the current study, neither of these were conducted on a nulliparous group and they failed to examine which risks were most likely to be missed. All risk factors had a poor compliance rate, but ethnicity was the risk factor most likely to be missed. The reason for such poor compliance is not clearly understood. Each hospital had a specific policy for screening of GDM. It appears that failure to identify the risk factor was the main reason that screening was not performed. Patient compliance or system failure did not appear to affect screening. Compliance within the recommended gestational time frame for screening was also poor. However, it is possible that some of the screening which occurred after the recommended gestational window may have been indicated by the development of a later pregnancy complication such as persistent glycosuria, a diagnosis of macrosomia or raised amniotic fluid on scan and may also account for those women who received screening without obvious risk factors. Unfortunately we were unable to investigate this as the data was not available to us in this study.

Risk based screening has been described in the literature as controversial, inadequate and inconsistent.(24, 25) These findings support the argument for universal screening or a more effective way of implementing risk based screening. When the compliance with risk based screening using NICE risk factors was assessed in the Irish cohort versus the UK cohort, the findings showed poorer compliance in the UK.

Strengths and Limitations

Strengths of this study include a high degree of completeness of the risk factor data in participants (99%). All risk factors recommended for screening from NICE were included in the SCOPE database as well as the two extra variables (age and PCOS) for Ireland. Rigorous

real time data monitoring protocols ensured data quality. Data were missing only in those women that suffered a late fetal loss (n=4).

The main limitation of this study is the inability to assess in detail why some women without NICE risk factors were screened. This may have been as a result of a risk that developed later in the pregnancy such as suspected macrosomia, polyhydramnios or persistent glycosuria. It was also not possible to determine from this study why women with a risk factor were missed. It is not known if those women were offered a GTT and declined or whether no screening was offered to women with risk factors. Also the generalizability of this population is questionable as it was a nulliparous, primarily Caucasian cohort, the results may not apply to high risk population.

Interpretation

Two percent of women within this cohort had a diagnosis of GDM which falls within previously published prevalence ranges of 1-14%. (6, 26) However, prevalence can vary widely depending on the population being screened and the diagnostic cut offs being used. (27) Also the true prevalence would likely to have been higher had all women with risk factors received screening. This study supports previous work which also showed poor compliance with local guidelines ranging from 31 to 61% appropriate risk based screening in Swedish and Thai cohorts respectively. (23, 28)

This study also is in keeping with an Irish national survey conducted at 19 units. Their aim was to assess implementation of local GDM screening guidelines. They reported that GTTs were performed at the recommended 24-28 weeks gestation in only 21% of units surveyed (n=4) of the cohort. (29) This study adds to literature describing the ineffectiveness of risk based screening. Even in units utilising NICE guidelines, which clearly state the risks which

predispose women to the development of GDM, an unacceptable proportion of women are not screened. We are unaware of previous studies that have assessed screening compliance of each risk factor individually as was undertaken in the present study.

Conclusion

In the UK and Irish SCOPE centres, where risk based screening is the assessment of choice, there was a low compliance rate. The risk factor missed most often was ethnic group. Further research could investigate the reasons affecting non-compliance, its effects on pregnancy outcomes and the alternative approach of universal screening. GDM may have lifelong adverse effects on the future health of both mother and baby. Accurate and complete screening and diagnosis is essential to improve outcomes.

Contributors

LCK is guarantor. NM, FMC, AK, and LCK designed the study and interpreted the data. LCK, NMM, FPMC, ASK, PMK, LP, NABS, JEM and RAG took part in drafting the article or revising it for critically important intellectual content and all gave final approval of the version to be published.

Ethical Approval

Ethical approval was obtained from local ethics committees [New Zealand AKX/02/00/364, Australia REC 1712/5/2008, London, Leeds and Manchester 06/MRE01/98 and Cork ECM5(10)05/02/08] and all women provided written informed consent.

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The authors did not report any potential conflicts of interest. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Competing interests

None declared.

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Figure 1: Legend

Flowchart demonstrating the screening pathway of the cohort with Glucose Tolerance Test and the subsequent diagnosis with Gestational Diabetes Mellitus.

Table 1: Legend

Descriptive statistics presented for the various baseline characteristics. Data are number (%).

*P values are for comparisons between the groups using chi-squared test, $P < 0.05$.

4 women were reported as late pregnancy loss therefore data unavailable.

**Manchester did not include ethnicity as a risk factor so their data was excluded from this calculation.

Table 2: Legend

Demonstrates the breakdown of GDM diagnosis for each centre using their own GTT cut off ranges.

	Screening cut off	Screened	Diagnosed GDM
Cork (n=1774)	Fasting ≥ 5.5 2 hour ≥ 7.8	532(30%)	44 (2.5%)
Leeds (n=144)	Fasting ≥ 5.5 2 hour ≥ 7.8	39(27%)	2 (2%)
Manchester (n=329)	Fasting ≥ 6.0 2 hour ≥ 9.0	67(20%)	3 (1%)
London (n=185)	Fasting ≥ 5.5 2 hour ≥ 9.0	18(10%)	5 (3%)
TOTAL =2432		656	54

21 **Table 3: Legend**

22 Percentage of women screened with a GTT in relation to the number of NICE risks they had.

	GTT Yes	GTT No	Missing Data (miss*/top**)	Total
0 Risk	261(40%)	1519(86%)	2	1782
1 Risk	323(49%)	223(12%)	2	548
2 Risks	68(10%)	29(2%)	0	97
3 Risks	4(1%)	1(0.05%)	0	5
Total	656	1772	4	2432

23

24 *Late miscarriage **Termination of pregnancy after initial study visit

25

Table 1: Characteristics of participants by Screened with a GTT and diagnosis of GDM

Variable	Not Screened with GTT N=1772 (73%)	Screened with GTT N=656 (27%)	P Value*	Of those screened No GDM N=601 (91.6%)	Of those screened GDM N=55 (8.4%)
<u>Maternal Age</u>			0.056		
14-19 years	77 (4)	12 (2)		11 (2)	1 (2)
20-39 years	1671 (94)	637 (97)		584 (97)	53 (96)
40+45 years	24 (1)	7 (1)		6 (1)	1 (2)
<u>Ethnicity**</u>			0.0001*		
White	1450 (96)	560 (95.1)		559 (93)	52 (95)
Asian	8 (0.5)	4 (0.7)		6 (1)	0
Indian	20 (1.3)	15 (2.5)		20 (3)	3 (5)
African	26 (1.7)	9 (1.5)		14 (2.3)	0
Pacific Islander	1 (0.1)	0 (0)		0	0
Other	6 (0.4)	1 (0.2)		2 (0.3)	0
<u>Body Mass Index</u>			0.0001*		
≤18.5	26 (1)	2 (0.3)		2 (0.3)	0
18.6-24.9	1160 (66)	263 (40)		253 (42.1)	10 (18.2)
25-29.9	498 (28)	180 (27)		161 (26.8)	19 (34.5)
≥30	88 (5)	211 (32)		185 (30.8)	26 (47.3)
<u>Socioeconomic Score</u>			0.265		
<24	270 (15)	117 (18)		106 (18)	11 (20)
≥24	1502 (85)	539 (82)		495 (82)	44 (80)

Variable	Not Screened with GTT N=1772 (73%)	Screened with GTT N=656 (27%)	P Value*	Of those screened No GDM N=601 (25%)	Of those screened GDM N=54 (2%)
<u>Alcohol</u>			0.272		
No alcohol in pregnancy	381 (21)	150 (23)		136 (23)	14 (26)
Quit in pregnancy	1077 (61)	404 (62)		372 (62)	32 (58)
Continued to drink alcohol	314 (18)	102 (15)		93 (15)	9 (16)
<u>Smoking</u>			0.936		
Never smoked	1294 (73)	473 (72)		433 (72)	42 (2)
Quit prior to 15 week visit	296 (17)	115 (18)		104 (17)	11 (20)
Continued to smoke	182 (10)	68 (10)		64 (11)	4 (7)
<u>Polycystic Ovarian Disease</u>			0.002*		
Yes	84 (5)	55 (8)		48 (8)	7 (13)
No	1688 (95)	601 (92)		553 (92)	43 (87)
<u>Family History Diabetes</u>			0.0001*		
Yes	106 (6)	217 (33)		195 (32)	22 (40)
No	1666 (94)	439 (67)		406 (68)	33 (60)
Type 1	14(1)	47 (7)		42 (7)	5 (9)
Type 2	92 (34)	176 (65)		158 (26)	18 (32.7)