

Prevalence and Incidence of Diabetic Retinopathy in Women with Gestational Diabetes and Overt Diabetes First Diagnosed in Pregnancy

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ABSTRACT

Objectives. Due to the lack of evidence linking retinopathy to gestational and overt diabetes, the utility of dilated fundus examination for screening is not established. This study aimed to determine prevalence and progression of retinopathy among newly diagnosed diabetic pregnant women.

Methodology. The study was a single-center observational, descriptive study at the outpatient department of a tertiary hospital. Newly diagnosed pregnant women were enrolled based on local criteria, using the 75-gram oral glucose tolerance test, HbA1C level, and random blood sugar test. Dilated fundus photo examination was used to document retinopathy. Fundus photo examination was done every trimester, at delivery and post-partum. Prevalence and incidence of diabetic retinopathy were measured and monitored.

Results. Seventy-one women were classified to have gestational diabetes and with no diabetic retinopathy on first consult and remained free of retinopathy during pregnancy and post-partum. In two women diagnosed with ODM, one showed sight-threatening diabetic retinopathy, was asymptomatic and had a visual acuity of 20/20.

Conclusion. GDM had no negative impact on retinal pathology and prevalence of diabetic retinopathy was higher among those with ODM. Our results suggest that screening in the GDM population is not advisable, and inconclusive in ODM.

Key Words: diabetes, pregnancy, retinopathy

INTRODUCTION

Diabetic retinopathy is a known sequela of uncontrolled diabetes due to hyperglycemic microvascular disease and is best documented in those with pregestational type 1 and type 2 diabetes. The American Academy of Ophthalmology (AAO) recommends retinopathy screening of patients previously diagnosed with type 1 and type 2 diabetes during pregnancy due to physiologic changes of pregnancy, which may affect control.¹ This recommendation is supported by a review of 11 related published studies, wherein sight-threatening progression of retinopathy was observed during pregnancy among pre-gestational type 1 and type 2 diabetics.²⁻¹¹

Local obstetric practice differentiates gestational diabetes (GDM) and overt diabetes (ODM). ODM is used to label pregnant women who fulfill the criteria for type 2 diabetes detected during pregnancy. In contrast, GDM is a state of glucose intolerance marked by lower fasting plasma glucose values.¹² There are no available studies that compare diabetic retinopathy outcomes among women with GDM

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and ODM diagnosed using local criteria. The AAO does not recommend diabetic retinopathy screening in women who develop gestational diabetes.¹ However, the evidence based on the recommendation uses different labels and diagnostic criteria, is not applicable to our local practice, and does not measure ophthalmologic outcomes. Despite the lack of applicable evidence, in local practice it has been common practice to subject newly diagnosed gestational diabetics and overt diabetics to dilated funduscopy and comprehensive examination. Thus, the purpose of the study is to determine the prevalence and incidence of diabetic retinopathy among those with gestational diabetes and overt diabetics first diagnosed in pregnancy.

OBJECTIVES

General Objective

To determine the prevalence and progression of retinopathy among newly diagnosed diabetic pregnant women

Specific Objectives

1. To determine the proportion of diabetic pregnant women with baseline retinopathy
2. To determine the distribution of retinopathy according to severity based on the International Clinical Diabetic Retinopathy Disease Severity Scale
3. To determine the proportion of retinopathies that progress throughout pregnancy
4. To determine the incidence of retinopathy among gestational and overt diabetic women during pregnancy until three months postpartum
5. To determine the proportion of retinopathies that persist until three months postpartum

MATERIALS AND METHODS

Study Design

The study design was a single-center observational, descriptive, prospective study with different phases conducted at the outpatient department of a tertiary hospital.

Outcomes

The primary outcomes of the study were prevalence and incidence of diabetic retinopathy using the International Clinical Diabetic Retinopathy Disease Severity Scale criteria.¹²⁻¹⁴ The secondary outcomes were prevalence and incidence of sight-threatening retinopathy:

1. Severe non-proliferative diabetic retinopathy or worse
2. Presence of center-involving diabetic macular edema.

Progression was defined as deterioration of at least one stage of diabetic retinopathy and/or development of diabetic macular edema in at least one eye.¹³

Study Population

Inclusion criteria

We included females of at least 18 years old, Filipino, carrying a singleton pregnancy, seen at the outpatient department of a tertiary hospital, newly diagnosed with diabetes mellitus at any trimester with consent seen at the Ophthalmology department of a tertiary hospital within 3 months of diagnosis of gestational diabetes.

The exposed population was composed of those who fulfilled the criteria for overt diabetes and gestational diabetes. Overt diabetes, based on the American Diabetes Association (ADA) and Philippine Obstetrics and Gynecology Society (POGS), was diagnosed in patients with any of the following criteria during their first prenatal visit:¹²⁻¹⁴

1. HbA1C \geq 6.5%,
2. Fasting blood glucose (FBS) \geq 126 mg/dL (fasting defined as no caloric intake for at least 8 hours),
3. 2-hour plasma glucose \geq 200 mg/dL during a 75-g anhydrous glucose tolerance test or
4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose of \geq 200 mg/dL.

Gestational diabetes, based on the American Diabetes Association (ADA) and Philippine Obstetrics and Gynecology Society (POGS), was diagnosed in patients with any of the following:¹²⁻¹⁴

1. a fasting blood sugar \geq 92 mg/dL, but $<$ 126 mg/dL at any gestational age
2. at 24–28 weeks AOG:
 - a. a 75-g anhydrous glucose tolerance test fasting blood sugar \geq 92 mg/dL, $<$ 126 mg/dL
 - b. 1-hour plasma blood glucose of 180 mg/dL, or
 - c. 2-hour plasma blood glucose of 140 mg/dL.

Exclusion criteria

The following were the exclusion criteria, based on their potential to confound the effect of pregnancy on blood glucose levels in the exposed populations:

1. Multifetal gestation at the current pregnancy
2. Diagnosed with any type of diabetes prior to pregnancy (pre-gestational diabetes)
3. History of previous treatment for gestational diabetes
4. Active chronic systemic disease
5. Seriously ill/high-risk pregnancies as diagnosed by an obstetrician
6. Women with history of retina treatment due to its potential to confound retinopathy findings
7. Patients who do not provide consent and minors will be excluded from the study

Sample Size Computation

The minimum sample size was computed using the formula for determining proportions at alpha of 0.05 and

precision of 0.05. With the expected prevalence of GDM and ODM of 5% in the sample, the minimum sample size needed was 72.

Patient Recruitment

Patients were recruited from the outpatient section of the obstetrics department of a tertiary hospital, with referrals from nurses and physicians, as they screened pregnant women for gestational diabetes. Pregnant women who fulfilled any of the criteria for overt diabetes and gestational diabetes as recommended by the Philippine Obstetrics and Gynecological Society (POGS) recommendations qualified for referral to the primary investigator for confirmation of eligibility and recruitment to the study (Appendices 1 and 2). Recruitment materials posted within the OB-OPD clinic and ophthalmology clinic were also used.

Prior to reviewing patient records, the primary investigator discussed the objectives and procedure of the study and obtained an informed consent. Once consent was obtained, records were reviewed, and patient history was obtained to confirm the patient's eligibility in fulfilling the study's inclusion criteria. Those who did not fulfill inclusion criteria or meet exclusion criteria were excluded from the study.

Data Collection and Procedures

History

Upon enrolment in the study, patients underwent a full ophthalmologic evaluation. Patient information and history was recorded on a standard data collection form. General information collected during the first examination included name, age, sex, race, address and contact number/s. Obstetric history pertinent to the patient's eligibility to the study was collected including number of fetal gestation and history of high-risk pregnancies. Past medical history pertinent to the patient's eligibility to the study was collected including history of pre-gestational diabetes, previous treatment for gestational diabetes, history of retina treatment, and active chronic systemic disease. Patients who fulfilled any of the exclusion criteria were excluded from the study.

Examination

After obtaining written consent, a comprehensive eye examination was performed, which included:

1. Visual acuity using the ETDRS visual acuity chart
2. Gross eye examination
3. Pupil examination
4. Extra ocular muscle motility
5. Slit lamp biomicroscopy
6. Goldmann applanation tonometry and
7. Dilated fundus examination using an indirect ophthalmoscope and 20 diopter lens

Findings during this evaluation were part of the hospital permanent records, and determined the need for subspecialist referral, clinic follow-up interval, and intervention. If signs of sight-threatening retinopathy were detected at any point during the follow-up period, patients were referred to the retina subspecialty service for appropriate management. Sight-threatening retinopathy included macular edema, signs of severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, optic nerve head neovascularization and/or neovascularization elsewhere, and vitreous or pre-retinal hemorrhage.

A variety of techniques can be used to detect and classify diabetic retinopathy, with mydriatic 7-field stereoscopic fundus color photography being the gold standard, as defined by the Early Treatment Diabetic Retinopathy Study (ETDRS) group.¹⁵ Patients underwent bilateral fundus photo within three months of their recruitment to the study. Fundus photo was performed by one certified technician using Topcon TRC-50EX retinal camera with pre-medication of tropicamide-phenylephrine, 1 gtt every 5 minutes for 3 doses, on each eye. Each fundus photo was interpreted by at least two retina consultants who were blinded to the patient's name and clinical diagnosis. In the event where two consultants had different diagnoses for a fundus photo, a third consultant was asked to read the fundus photo to arrive at a majority consensus on the diagnosis. Consultants used a standardized data collection checklist form.

The diagnosis and classification of diabetic retinopathy was based on the International Clinical Diabetic Retinopathy Disease Severity Scale.^{1,13,14} (Appendix 3) This severity scale is the current preferred classification of the American Academy of Ophthalmology, in an attempt to improve worldwide communication between ophthalmologists and primary care physicians.¹ It is based on the ETDRS classification of diabetic retinopathy and epidemiological studies of diabetic retinopathy. Macular edema was also diagnosed separately using the International Clinical Diabetic Macular Edema Disease Severity Scale.¹

Patient follow-up was every 3 months during pregnancy, if no retinopathy was noted, and more frequently if with severe diabetic retinopathy, as ordered by the co-managing retina specialist. The patient was also examined during their admission for delivery, with follow-up examinations comprising of visual acuity measurement and fundus photo. Post-delivery examination was scheduled if diabetic retinopathy was diagnosed during pregnancy.

Data Analysis

Using standard data collection forms, data was encoded, tabulated and computed in Microsoft Excel. Descriptive statistics were computed, including prevalence of baseline retinopathy and macular edema stage - categorized into severity, and incidence of retinopathy throughout the follow-up period, based on the International Clinical Diabetic

Retinopathy Disease Severity Scale. The proportion of retinopathies that progressed was measured; with progression defined as an increase in severity classification, or development of macular edema, based on the International Clinical Diabetic Retinopathy Disease Severity Scale. Proportion of sight-threatening progression was also measured, with sight-threatening progression defined as development of macular edema or progression to proliferative diabetic retinopathy.

Ethical Considerations

This study was conducted upon approval of the University of the Philippines Manila Ethics Research Board (UPMREB). The authors declared no conflict of interest relevant to the conduct of the study. This study was self-funded with partial compensation for equipment use by the Department of Ophthalmology.

Recruitment of patients were initiated by the OB OPD clinic nurses and physicians as well as through the use of poster promotional material. It was the primary investigator's responsibility to evaluate patient's eligibility to participate in the study upon acquisition of informed consent in adherence to the tenets of the Declaration of Helsinki. All patients were oriented of the entire procedure of the study prior to review of records, interview or ophthalmologic examination. Solely the primary investigator performed orientation and procurement of informed consent. Only patients of legal age and that were legally competent gave consent to the study. Minors were ineligible to participate in the study and thus, could not give consent. Those not legally competent to give consent were allowed to participate in the study with consent of her husband, legal guardian, parents, or next of kin. All patient information acquired in this study was kept anonymous and confidential.

Patients' names and clinical diagnoses remained blinded to evaluators of the fundus photos. Patients' names and clinical diagnoses were not blinded to the primary investigator and laboratory technician. All data were presented as part of consolidated data. Since baseline ophthalmologic examination was performed on all participants, patients were managed based on their ophthalmologic diagnosis free-of-charge and managed as any outpatient was at the general clinic and subspecialty clinics. Follow-up examinations that occurred outside of the study's timeline scope will be performed at the general clinic. Subspecialty care was performed at the respective subspecialty clinics. Further cost of management after referral was no longer covered by the primary investigator and sponsors. Compensation in the form of cash allowance for transportation was provided. As pregnancy category class C drugs, tropicamide and proparacaine have no established side effects to pregnancy. As such, expenses for the management of congenital or intrapartum adverse events would not be covered by the investigators. However, in the event that the patient (mother) incurs an adverse reaction to drugs used in the conduct of the study, the

investigators would shoulder the cost of treatment for the side effect. Patients could refuse ophthalmologic evaluation and management anytime in the course of the study.

RESULTS

A total of 73 patients participated in the study. Seventy-one were diagnosed with gestational diabetes and two with overt diabetes (Table 1). The mean age of gestation upon recruitment was in the third trimester for both groups. Expectedly, the mean fasting blood sugar levels were higher among overt diabetics.

Of the 73 patients, only one patient had any form of diabetic retinopathy upon first consult, with a prevalence of diabetic retinopathy between GDM and ODM of 1.5% (95% CI 0 to 8). This patient had sight-threatening retinopathy on both eyes. Thus, the prevalence of sight-threatening retinopathy at baseline (defined as those with findings of macular edema, signs of severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, optic nerve head neovascularization and/or neovascularization elsewhere, and vitreous or pre retinal hemorrhage) was similarly 1.5%.

Of the 73 patients with diabetes, 2 were classified as ODM. Of the 2, 1 had sight-threatening diabetic retinopathy upon recruitment and the other had none. The patient with retinopathy was diagnosed with a severe non-proliferative diabetic retinopathy without macular edema on her right eye. Her left eye was diagnosed with proliferative diabetic retinopathy with macular edema. She was referred to the retina subspecialty clinic for management but was lost to follow up. Both patients with overt diabetes were yet to deliver as of this publication.

Of the 73 recruited diabetic patients, 71 were classified as GDM. Fourteen of the patients were examined by indirect ophthalmoscopy but were unable to comply with fundus photo. All 14 patients did not have any signs retinopathy by clinical indirect ophthalmoscopy examination. The remaining 57 of the 71 patients diagnosed with GDM were examined clinically by indirect ophthalmoscopy and were able to comply with fundus photo examination upon enrollment to the study. All 57 patients showed no signs of diabetic retinopathy on first consult by both indirect ophthalmoscopy and by fundus photo. There was 100% agreement in readings of fundus photos between the consultants.

Among all 71 patients, 58 were not able to complete follow up every trimester, upon delivery and post-partum or were yet to deliver as of this publication. Thirteen of the 71 patients diagnosed with GDM completed follow-up until delivery or post-partum. All 13 patients did not have diabetic retinopathy on first consult, during follow-up and no new-onset diabetic retinopathy was detected upon delivery or post-partum.

Table 1. Baseline characteristics of patients

	Gestational Diabetes Mellitus (n=71)	Overt Diabetes Mellitus (n=2)
Mean age, years	31 (20-44)	35
Mean gravidity, n	2.48 (1-8)	3.5 (3-4)
Mean AOG on recruitment, weeks	32 1/7 (18 2/7 - 41 3/7)	34 1/7 (33 4/7 - 34 5/7)
Mean HbA1C (%)	4.8	6.55 (6.5-6.6)
Mean RBS (mg/dL)	116.31 (94.6-181.57)	106.2
Mean 75-g OGTT		
FBS (mg/dL)	81.22 (53.57-153.57)	105.3
1-hour (mg/dL)	177.32 (103-328.9)	230
2-hour (mg/dL)	151.96 (42.35-310)	226.44
By Either Fundus Photo OR Indirect Ophthalmoscopy		
Without any retinopathy	71	1
With any retinopathy	0	1
With sight-threatening retinopathy	0	1
By Fundus Photo AND Indirect Ophthalmoscopy		
Without any retinopathy	57*	1
With any retinopathy	0	1
With sight-threatening retinopathy	0	1

*14 patients were not able to comply with fundus photo examination upon diagnosis

Table 2. Comparison of baseline characteristics

	Gestational Diabetes Mellitus		Overt Diabetes Mellitus	
	Rogelio (n=71)	Sugiyama (n=1267)	Rogelio (n=2)	Sugiyama (n=348)
Mean age, years	31 (20-44)	33.6 ± 4.8	35	33.1 ± 5.3
Mean AOG on recruitment, weeks	32 1/7 (18 2/7 - 41 3/7)	23.5 ± 8.2	34 1/7 (33 4/7 - 34 5/7)	22.0 ± 9.0
Mean HbA1C (%)	4.8	5.8 ± 0.5	6.55 (6.5-6.6)	6.8 ± 1.1
Mean 75-g OGTT				
FBS (mg/dL)	81.22 (53.57-153.57)	90.5 ± 11.8	105.3	114.5 ± 32.2
1-hour (mg/dL)	177.32 (103-328.9)	200.8 ± 32.1	230	237.2 ± 47.1
2-hour (mg/dL)	151.96 (42.35-310)	177.7 ± 34.2	226.44	227.6 ± 43.5
Retinopathy on first consult, n (%)	0	0	1 (50)	4 (1.2)

DISCUSSION

The absence of diabetic retinopathy among gestational diabetics both upon recruitment and on follow up suggests that gestational diabetes may have no negative impact on retinal pathology. However, this statement is limited by the relatively small sample size and poor follow-up rate upon delivery and post-partum. Also, since the study was descriptive, no correlation was made between blood sugar levels, retinopathy or visual acuity - but which could be explored in future studies.

The patient who did present with diabetic retinopathy was a 35-year-old G3P2(2002) with no systemic symptoms suggestive of diabetes, no visual symptoms, no eye surgery and was never worked up for diabetes pre-gestationally or in previous pregnancies. She was diagnosed to have overt diabetes mellitus on the basis of an HbA1C of 6.6%

measured at her first trimester and on the basis of her 2-h FBS of 226.44 mg/dL on her third trimester. Despite lack of symptoms suggestive of diabetes, the absence of pre-gestational work-up for diabetes, and a diagnosis of overt diabetes mellitus, we cannot exclude the possibility of pre-gestational diabetes in this patient. The possibility of pre-gestational diabetes in our patient is consistent with the sight-threatening diabetic retinopathy seen on fundus photo since prevalence of diabetic retinopathy is associated with longer duration of uncontrolled diabetes. Even with sight-threatening retinopathy, this patient's vision upon recruitment was 20/20. This suggests that even with a negative impact on retinal pathology, vision may remain unaffected, suggesting that vision may be a poor parameter to guide screening guidelines.

Though the first study of its kind to describe prevalence, progression and incidence of diabetic retinopathy among

those diagnosed with GDM and ODM using locally used diagnostic criteria (POGS), the characteristics and results of this study are comparable to Sugiyama's.¹¹ The comparison of baseline characteristics is seen in Table 2.

Both studies detected no diabetic retinopathy among those diagnosed with GDM despite having disparate sample sizes. This suggests that the routine screening of diabetic retinopathy among those classified to have GMD alone may not be warranted and that GDM may not have a negative impact on vision. Though prevalence of retinopathy among those with ODM is higher than those with GDM, the utility of this information is limited since it does not correlate progression, visual acuity or symptoms. In addition, our sample size was too small and patients had poor follow up rate to draw any conclusions regarding ODM. We suggest a prospective observational study measuring incidence and progression over the course of pregnancy to better evaluate the need for screening.

CONCLUSION

Sight-threatening retinopathy was noted in a single patient with ODM, presenting with 20/20 vision. Due to small sample size and poor follow-up, the utility of routine screening among ODM pregnant is inconclusive. Affecting only 1 in 73 patients, our study shows that overall prevalence of diabetic retinopathy among pregnant diabetics is 1.5%. Patients with GDM had no retinopathy and had no progression until post-partum. This suggests that there is no negative impact on retinal pathology, thus making routine screening in the GDM population not advisable.

Statement of Authorship

PAR contributed in the conceptualization, protocol formulation, patient recruitment, data collection, data analysis, paper-writing and drafting of all versions.

DES contributed in the conceptualization, data collection and interpretation, evaluation, review of all drafts and final version.

Both authors approved the final version submitted.

Author Disclosure

Both authors declared no conflicts of interest.

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APPENDICES

Appendix 1. Fifth International Workshop-Conference on Gestational Diabetes: Recommended Screening Strategy Based on Risk Assessment for Detecting Gestational Diabetes (GDM)

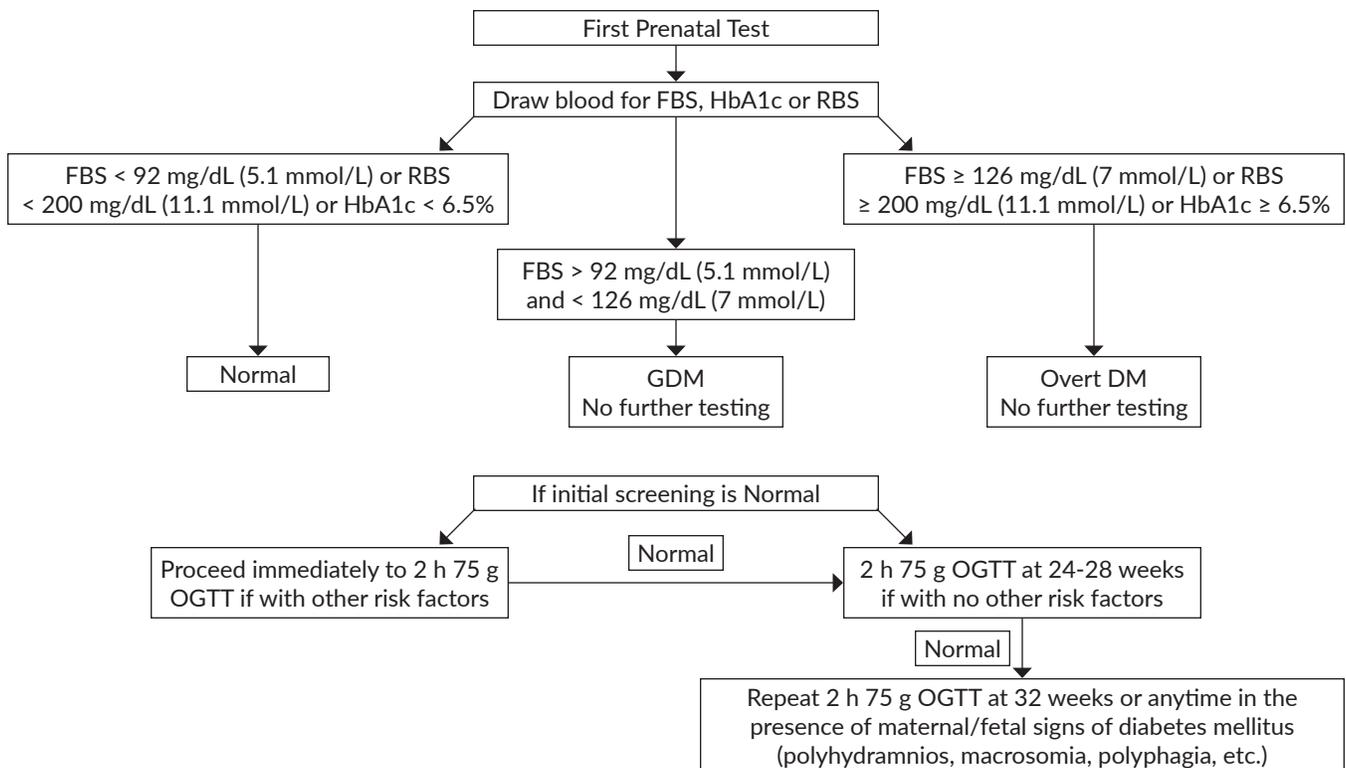
GDM risk assessment: Should be ascertained at the first prenatal visit

Low Risk: Blood glucose testing not routinely required if all the following are present:
 Member of an ethnic group with a low prevalence of GDM – No known diabetes in first-degree relatives
 Age < 25 years
 Weight normal before pregnancy
 Weight normal at birth
 No history of abnormal glucose metabolism
 No history of poor obstetrical outcome

Average Risk: Perform blood glucose testing at 24 to 28 weeks using either
 Two-step procedure: 50-g oral glucose challenge test (GCT), followed by a diagnostic 100-g oral glucose tolerance test for those meeting the threshold value in the GCT.
 One-step procedure: Diagnostic 100-g oral glucose tolerance test performed on all subjects.

High Risk: Perform blood glucose testing as soon as feasible, using the procedures described above if one or more of these are present:
 Severe obesity
 Strong family history of type 2 diabetes
 Previous history of GDM, impaired glucose metabolism, or glycosuria. If GDM is not diagnosed testing should be repeated at 24-28 weeks or at any time there are symptoms or signs suggestive of hyperglycemia.

Modified from Metzger and Colleagues (2007); Copyright © 2007 American Diabetes Association. From Diabetes Care®, Vol. 30; 2007, S251-S260.



Appendix 2. Recommendations for Filipino Women Based on POGS CPG Consensus on Diabetes Mellitus in Pregnancy, 2011. Protocol for Evaluation of Diabetes in Pregnant Filipino Women.

Appendix 3.

TABLE 1 DIABETIC RETINOPATHY DISEASE SEVERITY SCALE AND INTERNATIONAL CLINICAL DIABETIC RETINOPATHY DISEASE SEVERITY SCALE

Disease Severity Level	Findings Observable upon Dilated Ophthalmoscopy
No apparent retinopathy	No abnormalities
Mild NPDR (see Glossary)	Microaneurysms only
Moderate NPDR (see Glossary)	More than just microaneurysms but less than severe NPDR
Severe NPDR	
U.S. Definition	Any of the following (4-2-1 rule) and no signs of proliferative retinopathy: <ul style="list-style-type: none"> • Severe intraretinal hemorrhages and microaneurysms in each of four quadrants • Definite venous beading in two or more quadrants • Moderate IRMA in one or more quadrants
International Definition	Any of the following and no signs of proliferative retinopathy: <ul style="list-style-type: none"> • More than 20 intraretinal hemorrhages in each of four quadrants • Definite venous beading in two or more quadrants • Prominent IRMA in one or more quadrants
PDR	One or both of the following: <ul style="list-style-type: none"> • Neovascularization • Vitreous/preretinal hemorrhage

IRMA = intraretinal microvascular abnormalities; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy

NOTE:

- Any patient with two or more of the characteristics of severe NPDR is considered to have very severe NPDR.
- PDR may be classified as high-risk and non-high-risk. See Table 6 for more information.

Adapted with permission from Wilkinson CP, Ferris FL III, Klein RE, et al. Proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales. *Ophthalmology* 2003;110:1679.

TABLE 2 INTERNATIONAL CLINICAL DIABETIC MACULAR EDEMA DISEASE SEVERITY SCALE

Proposed Disease Severity Level	Findings Observable upon Dilated Ophthalmoscopy
Diabetic macular edema apparently absent	No apparent retinal thickening or hard exudates in posterior pole
Diabetic macular edema apparently present	Some apparent retinal thickening or hard exudates in posterior pole
If diabetic macular edema is present, it can be categorized as follows:	
Proposed Disease Severity Level	Findings Observable upon Dilated Ophthalmoscopy*
Diabetic macular edema present	<ul style="list-style-type: none"> • Mild diabetic macular edema: some retinal thickening or hard exudates in posterior pole but distant from the center of the macula • Moderate diabetic macular edema: retinal thickening or hard exudates approaching the center of the macula but not involving the center • Severe diabetic macular edema: retinal thickening or hard exudates involving the center of the macula

Reproduced with permission from Wilkinson CP, Ferris FL III, Klein RE, et al. Proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales. *Ophthalmology* 2003;110:1680.

* Hard exudates are a sign of current or previous macular edema. Diabetic macular edema is defined as retinal thickening; this requires a three-dimensional assessment that is best performed by dilated examination using slit-lamp biomicroscopy and/or stereoscopic fundus photography. Optical coherence tomography may supplement the fundus evaluation for determining the presence of diabetic macular edema.

Taken from American Academy of Ophthalmology. *Preferred Practice Pattern: Diabetic Retinopathy*. American Academy of Ophthalmology, 2014: 7-9.