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Original research

A new predictive tool for the early risk assessment of gestational diabetes mellitus

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ABSTRACT

Aims: The Italian National Institute of Health has recently introduced a selective screening based on the risk profile of pregnant women, which while recommending against screening of women at low risk (LR) for GDM, it recommends an early test for women at high risk (HR) for GDM. Herein, we assessed the accuracy and cost-effectiveness of this screening and developed a new index that improves these requirements.

Methods: We retrospectively enrolled 3974 pregnant women. GDM was diagnosed with a 2 h 75-g OGTT at 16–18 weeks (early test) or 24–28 weeks of gestation, according to the IADPSG guidelines.

Results: 55.6% of HR women had GDM, although only 38.4% underwent early screening. Among 2654 women at medium risk, 20.9% had GDM; paradoxically, among 770 LR women, that would not have been screened, 26.6% received a GDM diagnosis. Based on these unsatisfactory results, we elaborated the Capula's index, that reduced both screening tests ($p < 0.001$) and potentially undetected GDM cases ($p < 0.001$), and corrected the paradoxical prevalence estimates of GDM obtained with the current Italian guidelines. Also, Capula's index improved correlation of GDM risk profile with obstetric and neonatal adverse events.

Conclusions: Capula's index improves accuracy of selective screening for GDM.

Abbreviations: GDM, gestational diabetes mellitus; IADSPG, International Association Diabetes Pregnancy Study Groups; LR, low risk; MR, medium risk; HR, high risk; FPG, fasting plasma glucose; BMI, body mass index; PCOS, polycystic ovary syndrome.

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1. Introduction

Gestational diabetes mellitus (GDM) is an important emerging healthcare problem; which represents a major risk factor for both maternal and neonatal adverse events [1]. Its incidence is increasing globally; causing significant economic burden worldwide [2]. In an attempt to reduce the great impact of GDM on materno-fetal complications; in 2010; the International Association of Diabetes and Pregnancy Study Group (IADPSG) panel established more rigorous glycemic criteria and recommended the universal screening for the diagnosis of GDM [3]. It consists of a 75-g oral glucose tolerance test (OGTT) to be performed at 24–28 weeks of gestation in all pregnant women [3]. This indication has been adopted by the WHO [4]; by the American Diabetes Association (ADA) [5]; and by the American Association of Clinical Endocrinologists (AACE) [6]. However; to avoid overdiagnosis of GDM and limit national healthcare system costs; several international medical societies have proposed selective screening based on individual risk assessment [7–9]; and this has led to a disparity in screening recommendations for GDM among countries; as well as within countries [10]. In this context; in July 2011; the Italian National Institute of Health (ISS) has issued new guidelines; which recommend a selective screening for GDM based on pregnant risk profile (www.salute.gov.it); by using a 75-g OGTT with glucose cut-off points according to IADPSG. In particular; a 2h-OGTT must be carried out early in pregnancy (16–18 weeks) in women at high risk (HR) for GDM [previous GDM; pre-pregnancy body mass index (BMI) $\geq 30\,kg/m^2$; fasting plasma glucose (FPG) at first visit or before pregnancy between 100 and 125 mg/dl (5.6–6.9 mmol/L)]. All pregnant women at medium risk (MR) [age ≥ 35 years; pre-pregnancy BMI between 25.0 and 29.9 kg/m^2; previous macrosomia; family history of type 2 diabetes mellitus in first grade relatives; at-risk ethnic group (*e.g.* South Asian; Black Caribbean; and Middle Eastern)]; as well as women with negative results on early OGTT; are required to undergo the OGTT later in pregnancy (24–28 week). No screening is indicated for women not matching the above mentioned criteria; who; therefore; are considered at low risk (LR) for GDM.

Although less sensitive than IADPSG criteria in identifying women with GDM in our population [11], the Italian recommendations, however, have their strongest impact on the early screening for women who are at HR for developing GDM, in which timely treatment of this condition could help to prevent adverse maternal and neonatal outcomes [12]. The present study estimates the accuracy of Italian guidelines for the management of GDM, and proposes a new index for their improvement.

2. Methods

2.1. *Study population*

This is a retrospective population-based study involving 3974 consecutive pregnant women attending the Operative Unit of

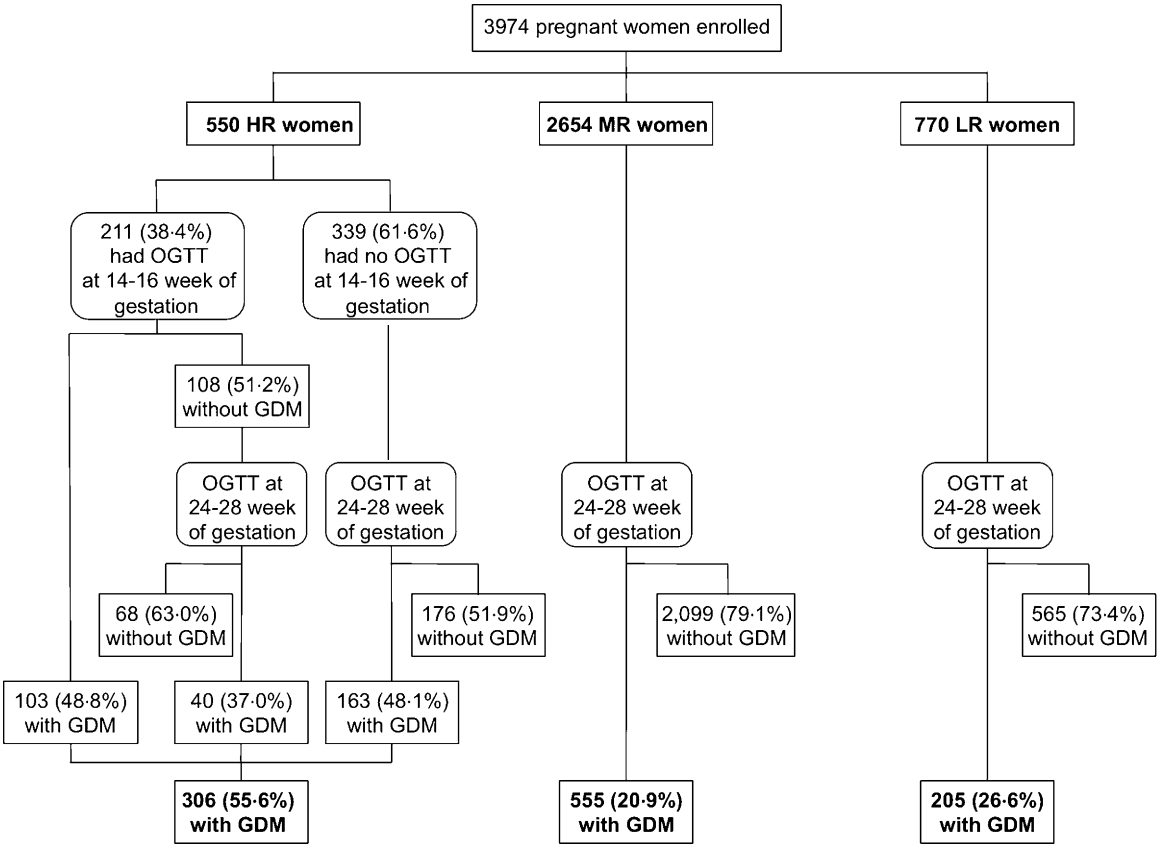

Fig. 1 – Classification of pregnant women according to the Italian guidelines risk profile and relative prevalence of GDM after OGTT.