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Use of Electronic Instruments for the Opportunistic Screening of Undiagnosed Diabetes and Other Disorders of Glucose Metabolism. The Diabetes Screening Palermo Study "D.S.P.S."

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Abstract ***Introduction***: The Diabetes Screening Palermo Study evaluated, in the general practice setting, the effectiveness of a screening strategy for type 2 diabetes mellitus (T2DM). This study used electronic instruments to identify individuals at a high risk of diabetes and to provide early detection of undiagnosed T2DM and prediabetes. ***Methods and results***: This is an observational study in primary care from Italy. The screening programme was divided into two phases. Phase 1: identification of patients at high risk of diabetes through the analysis of databases of general practitioners. Phase 2: screening to test for diabetes or prediabetes using fasting plasma glucose (FPG) and the 2-h plasma glucose value after a 75-g oral glucose tolerance test (OGTT). The OGTT was a central component of the screening programme and a significant proportion of individuals at high risk for diabetes, which is defined as those with impaired fasting glucose (IFG), had blood glucose levels, after the glucose load that either were compatible with a diagnosis of T2DM or impaired glucose tolerance (IGT). Results after 24 months of the study: the total study was composed of 26 410 subjects, of which 13 319 (50.43%) were at high risk of T2DM. 8174 subjects, representing the 61,37% of those at high-risk, had at least one measurement of fasting plasma glucose (FPG). A total of 5428 subjects equal to 66,41% of those with at least one measurement of fasting blood glucose and equal to 40.75% of all high-risk subjects, had impaired fasting glucose (IFG) A sample of 965 subjects with IFG, were then subjected, at random, to an OGTT, on the basis of which 136 subjects (14.09%) were identified with IGT and 83 subjects (8.60%) gave a response compatible with the diagnosis of T2DM. ***Conclusion***: In a primary care setting, a proactive approach towards diabetes screening, especially performing OGTT in subjects with IFG, facilitated the early diagnosis of T2DM. This reduced the percentage of cases of undiagnosed diabetes and allowed the identification of individuals with prediabetes who required preventive interventions. Through a process of clinical audit, the computerised systems, facilitated the identification of people at high risk for diabetes and led to better management of the screening programme.

Keywords Diabetes screening, People at high risk of diabetes, Disorders of glucose metabolism, Oral glucose Tolerance Test (OGTT), Computerised systems

1. Introduction

Type 2 diabetes (T2DM) is a chronic disease with a high prevalence and constant growth. Data from the eighth report of the Health Search from the Research Institute of the Italian Society of General Practitioners (SIMG) in 2013-2014 [1] showed a trend of increasing prevalence from 5.9% in 2005 to 7.7% in 2013. The prevalence grows with age; one in five people above 75 years of age suffers from diabetes. The prevalence of diabetes is also higher in obese and overweight individuals, as well as those who are not physically active [2].

Data from the literature also shows that in 30-50% of cases, diabetes is not diagnosed [3] and that the diagnosis of diabetes is often delayed. An early diagnosis would allow for therapeutic intervention with positive results in terms of the prevention of long-term complications [4, 5].

It is widely accepted that the clinical diagnosis of T2DM is preceded by a long asymptomatic phase during which the disease can only be diagnosed if actively detected through screening procedures.

The screening programme should be directed at the population at high risk of diabetes (selective screening) and performed during a medical check-up (opportunistic screening) [3].

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Testing should be carried out, within a health care setting. Community testing outside a health care setting is not recommended because people with positive tests may not seek or have access to appropriate follow-up testing and care. Community testing may also be poorly targeted, i.e., it may fail to reach the groups most at risk and inappropriately test those at very low risk or even those who have already been diagnosed [6].

The screening programme also allows the detection of other disorders of glucose metabolism, such as impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) [7], all of which predict the future development of the disease and therefore require appropriate preventive interventions that are based primarily on lifestyle changes. The effects of lifestyle interventions to prevent or delay progression to diabetes were consistent across a substantive body of literature [8, 9].

Primary care is widely considered the prime setting to implement opportunistic screening programmes for early detection of T2DM and prediabetes.

Currently, the general practitioners (GPs) use computer systems to allow them to identify people at high risk of diabetes easily and to manage the entire screening programme proactively.

Within the context of the SIMG of Palermo, a study (Diabetes Screening Palermo) has been designed to evaluate the effectiveness of a screening strategy, which uses electronic instruments to allow easy identification of people at high risk for diabetes and to provide early diagnosis of T2DM and prediabetes.

2. Methods

Twenty GPs of SIMG conducted an observational study, between September 2013 and August 2015, in the Italian region of Sicily in the Province of Palermo. The study participants were drawn from the general patient population of these physicians. Included were men and women, aged > 14 years, after the exclusion of individuals previously diagnosed with diabetes

The screening programme was carried out in two phases:

1st phase: identification of people at high risk for diabetes through the analysis of databases of the general practitioners.

2nd phase: screening for early diagnosis of T2DM and other disorders of glucose metabolism (IFG, IGT).

To identify those at high risk for T2DM, the criteria adopted was from the Italian Standard of Medical Care in Diabetes 2014 (3). Adults, of any age, who were obese or overweight (BMI ≥25 kg/m^2) and who had one or more additional risk factors for diabetes, were considered as being at high risk for diabetes (Table 1). For all patients, without these risk factors, testing began at age 45.

Risk factors were considered: physical inactivity; first-degree relative with diabetes; women who delivered a baby weighing >9 lb or were diagnosed with GDM; hypertension (>140/90 mmHg or on therapy for hypertension); HDL cholesterol level <35 mg/dL (0.90 mmol/L) and/or a triglyceride level <250 mg/dL (2.82 mmol/L); women with polycystic ovary syndrome; HbA1C =>5.7%, IGT or IFG on previous testing; other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans); history of CVD.

Testing for diabetes or prediabetes used HbA1c, fasting plasma glucose (FPG) and the 2-h plasma glucose value after a 75-g oral glucose tolerance test (OGTT). [10] (Figure 1).

The HbA1c test was standardized with the new method of the IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and expressed in mmol/mol [11, 12].

Excluded were conditions which may interfere with the measurement and interpretation of HbA1c, including hemoglobinopathies, anaemia, recent transfusion, splenectomy, uraemia, severe hyperbilirubinemia, severe hypertriglyceridemia, severe leukocytosis, or alcoholism. In these conditions, diagnosis of diabetes relied only on the blood glucose criteria [13].

Blood glucose <100 mg% was considered normal glucose tolerance (NGT).

When the fasting blood sugar was => 126 mg% or HbA1c => 48 mmol / mol, (confirmed on at least two different occasions, where there were absent disease symptoms), the diagnosis was T2DM.

If the fasting blood sugar was between 100 and 125 mg% (IFG), an oral glucose tolerance test (OGTT) was performed.

The OGTT was a central component of the screening programme because a significant proportion of individuals at high risk for diabetes, which is defined as those with impaired fasting glucose (IFG), had 2-h plasma glucose value, after a 75-g oral glucose load, that either were compatible with a diagnosis of T2DM or impaired glucose tolerance (IGT) [14, 15].

The screening programme also provided for active follow-up. People with IFG or IGT were subjected to annual retest. Subjects with NGT will be retested after 3 years [3-16].

The rationale for the 3-year interval is that the number of false-positive tests that require confirmatory testing will be reduced, but individuals with false-negative tests will be retested before a substantial time elapses and complications develop [17].

Physicians participating in the study used the medical record Millewin, [18] and the software MilleGPG, General Practice Governance (by Millennium Srl, Florence-Italy) [19], two computer systems developed to the professional specifications of the Italian Society of General Medicine. These interacting systems use a panel of indicators to allow the monitoring of clinical activity and highlight any clinical or managerial problems, thereby allowing the physician to make the necessary corrections.

In MilleGPG, physicians have created a local audit project, (Audit Palermo), which includes 9 main indicators (AP 01-AP 09) and 30 other indicators for monitoring of subgroups that are broken down by gender, age and BMI.

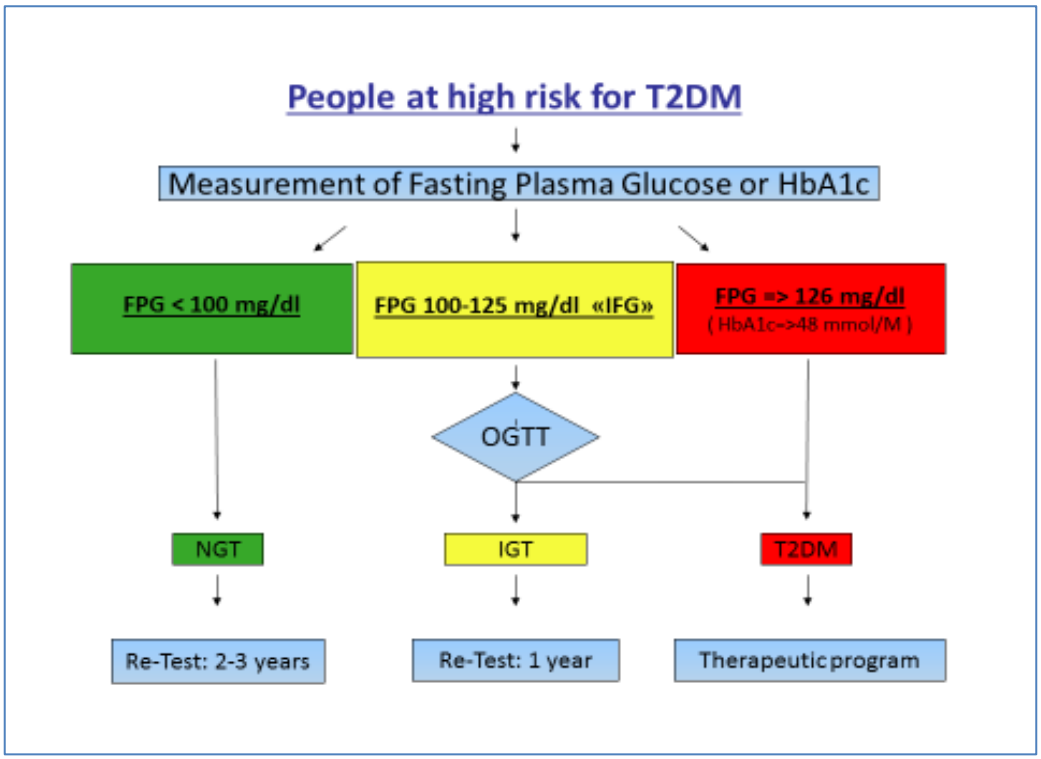
Among the main indicators, AP 01 identifies subjects at high risk of diabetes, indicator AP 02 identifies those with, at least, one measurement of fasting blood glucose, indicator AP 04 identifies subjects with a new diagnosis of diabetes based on HbA1c criteria (e.i. >= 6.5%) and/or fasting plasma glucose criteria (i.e. >= 126 mg/dl). Still other indicators identify subjects with IFG, those with IFG who underwent an OGTT, and how many of these latter subjects had a new diagnosis of T2DM or IGT.

Moreover, some indicators identify deficits of testing. Indicator AP 03 identifies high-risk individuals without a recording of fasting blood glucose. Indicator AP 07 identifies subjects with IFG who did not undergo an OGTT.

Consequently, when doctors open the medical record in Millewin, clinical reminders notify them, if a person at risk for diabetes was not required to have a fasting blood glucose record or if a person with IFG was not required to take the OGTT. Thus, the doctors intervene by requiring these tests.

For each indicator, it was also possible to carry out personal and group audits, with the possibility of benchmarking among physicians participating in the study.

The GPs used the computer systems available and led the screening programme with a proactive approach and in accordance with the principles of medical initiative.



T2DM: type 2 diabetes mellitus; HbA1c: glycated haemoglobin; FPG: fasting plasma glucose; OGTT: Oral glucose Tolerance Test; NGT: normal glucose tolerance; IFG: impaired fasting glucose; IGT: impaired glucose tolerance

Figure 1. Screening procedure and the follow up of the subjects at high risk for T2DM

Table 1. Values of the main indicators, after 24 months of the DSP Study

Indicator code	Description	Numerator	Denominator	Total
AP-01	People at high risk for T2DM (Type 2 Diabetes Mellitus)	13319	26410	50,43%
AP-02	People at high risk for T2DM with at least one measurement of FPG (Fasting Plasma Glucose)	8174	13319	61,37%
AP-03	People at high risk for T2DM without at least one measurement of FPG (Fasting Plasma Glucose)	5145	13319	38,63%
AP-04	People with FPG (fasting plasma glucose) > = 126 mg/dL and/or HbA1c > = 6.5% and diagnosis of T2DM	49	13319	0,37%
AP-05	People with IFG (Impaired Fasting Glucose)	5428	8174	66,41%
AP-06	People with IFG (Impaired Fasting Glucose) subjected to OGTT (Oral Glucose Tolerance Test)	965	5428	17,78%
AP-07	People with IFG (Impaired Fasting Glucose) not subjected to OGTT (Oral Glucose Tolerance Test)	4463	5428	82,22%
AP-08	Diagnosis of T2DM, in people with IFG (Impaired Fasting Glucose) subjected to OGTT (Oral Glucose Tolerance Test)	83	965	8,60%
AP-09	Diagnosis of IGT (Impaired Glucose Tolerance) in people with IFG (Impaired Fasting Glucose) subjected to OGTT (Oral Glucose Tolerance Test)	136	965	14,09%

3. Results

Table 1 shows the numerical values of the nine core indicators, after 24 months of the study.

The study was composed of 26 410 subjects, of which 13 319 (50.43%) were at high risk for T2DM.

A total of 8174 subjects, representing the 61,37% of those at high-risk, had at least one measurement of fasting plasma glucose (FPG).

A total of 5428 subjects equal to 66,41% of those with at least one measurement of fasting blood glucose and equal to 40.75% of all high-risk subjects, had impaired fasting glucose (IFG) (Fig 2).

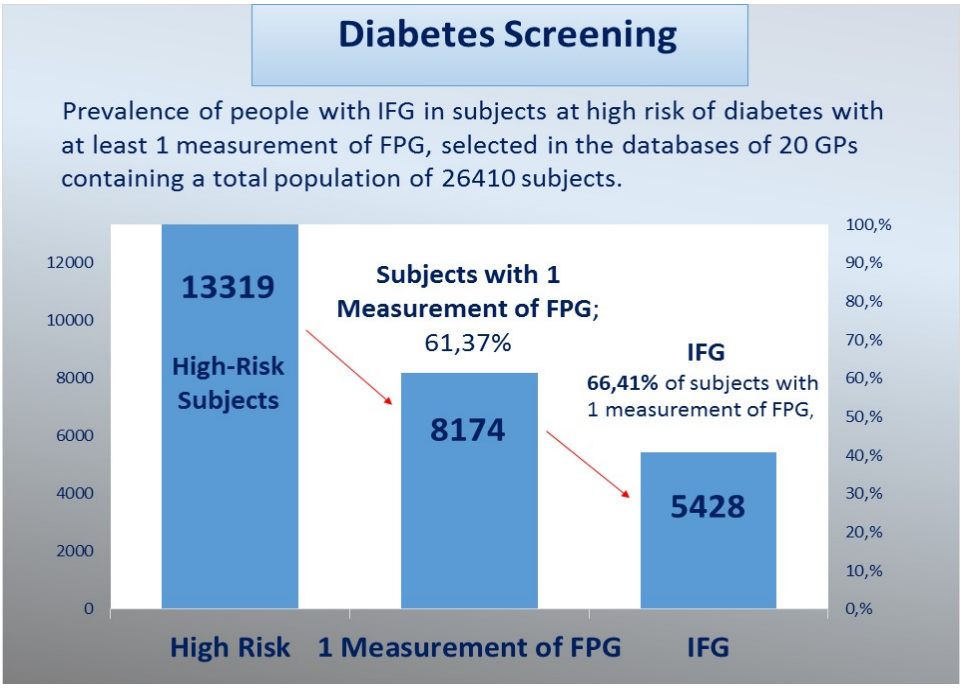


Figure 2. Prevalence of IFG in the population at high risk for T2DM selected in the database of 20 GPs, containing a total population of 26 410 subjects, in the DSP Study

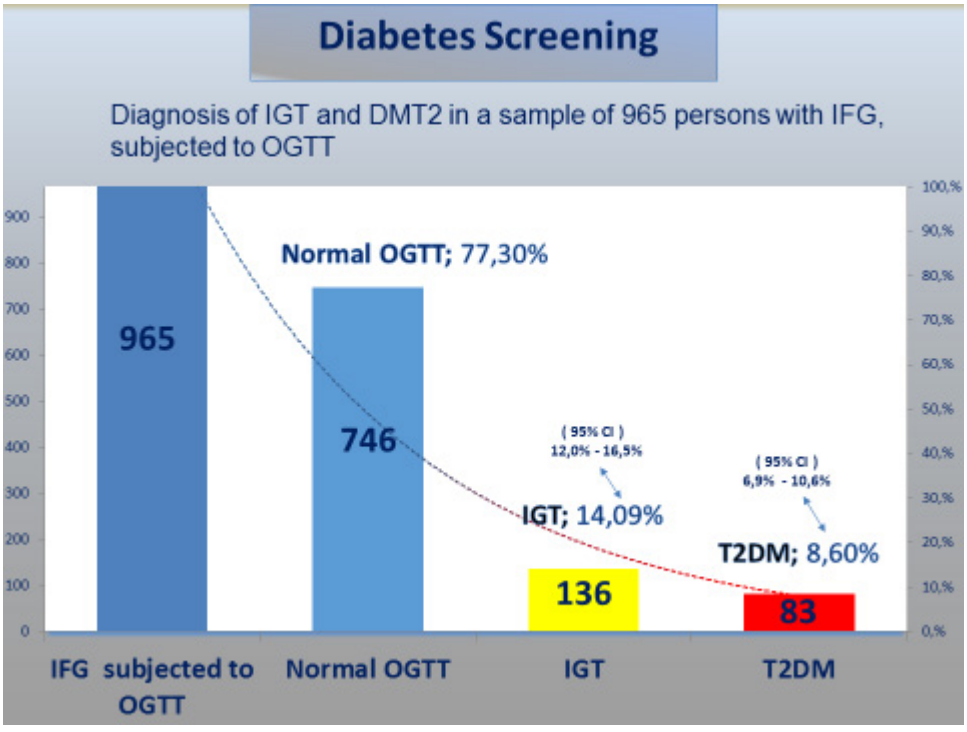


Figure 3. Diagnosis of IGT and DMT2 in a sample of 965 individuals with IFG, subjected to an OGTT. The percentages of IGT and T2DM were calculated with a confidence interval of 95%

Table 2. Analysis by gender, age and BMI in subjects with IGT or T2DM diagnosed based on an OGTT in the DSP Study

Diabetes Screening

Analysis by Gender, Age and BMI

	IFG subjected to OGTT		IGT		T2DM	
	N	%	N	Prevalence	N	Prevalence
GENDER						
Males	500	51,81	69	13,80	43	8,60
Females	465	48,19	67	14,41	40	8,60
AGE						
Age<45	85	8,81	2	2,35	4	4,71
Age 45-54	147	15,23	13	8,84	8	5,44
Age 55-64	265	27,46	28	10,57	18	6,79
Age 65-74	285	29,53	53	18,60	21	7,37
Age≥75	183	18,96	40	21,86	32	17,49
BMI						
BMI < 25	165	17,10	14	8,48	9	5,45
BMI ≥25 <30	441	45,70	67	15,19	40	9,07
BMI ≥ 30	359	37,20	55	15,32	34	9,47
TOTAL	965	100	136	14,09	83	8,60

This prevalence aligned with data from the international literature after lowering the threshold of normal fasting blood glucose from 110 to 100 mg% [20, 21].

A sample of 965 subjects with IFG, (equal to 17.78% of the cohort with IFG), was, at random, subjected to an OGTT, on the basis of which 136 subjects (14.09%) were identified with IGT, and 83 subjects (8.60%) gave an OGTT response compatible with the diagnosis of T2DM. The percentages were calculated with a confidence interval of 95% (Fig. 3).

Subjects with IGT and T2DM diagnosed based on an OGTT were also analysed by gender, age and BMI (Table 2).

Analysis by age showed that the prevalence of IGT and T2DM increases with age, with a maximum in the age range greater than 75 years.

BMI analysis showed that the prevalence of IGT and T2DM is greater in overweight and obese subjects than in normal weight subjects.

This data confirms the importance of increased age and being overweight or obese as major risk factors for IGT and T2DM.

4. Discussion

Facilities for Diabetes diagnosis and management should be available in primary health-care settings, with an established referral and back-referral system.

The use of electronic databases to identify subjects at high risk of diabetes has resulted in the development of algorithm/prediction models in several countries. The main goal of these studies is, in general, to define patients' characteristics associated with a higher probability of having diabetes, i.e. patients for whom performing a blood test is justified. The Diabetes Screening Palermo Study, confirmed that, through a process of clinical audit, the computerised systems, used by GPs, facilitated the identification of people at high risk for diabetes and moreover improved the management of the screening programme. These computer systems used a panel of indicators that allowed the monitoring of clinical activity and highlighted any clinical or managerial problems, thereby allowing the physician to make the necessary corrections and to lead the screening programme with a proactive approach.

Primary care remains the most favourable setting for an early diagnosis of diabetes. A systematic and proactive approach towards diabetes screening, especially by performing OGTT in subjects with IFG, facilitated, in the Diabetes Screening Palermo Study, the early diagnosis of T2DM. The prevalence of 8.60% of subjects with T2DM diagnosed based on an OGTT could be extended to all subjects with IFG identified in the study, using the OGTT.

Similarly, If this screening model was applied through a joint action of the Italian regions or European countries, the result would be a global reduction of undiagnosed diabetes and the identification of a large population of patients with prediabetes (IFG or IGT), requiring preventive interventions based primarily on lifestyle changes [22-24].

GPs partecipating in the study: Tindaro Iraci, Salvatore Campo, Girolamo Consiglio, Rosario D'Alessandro, Vittorio Di Carlo, Baldassare Di Silvestre, Serenella Fasulo, Luigi Galvano, Francesco Paolo Lombardo, Francesco magliozzo, Giuseppa Mazzola, Vincenzo Mazzola, Giovanni Merlino, Umberto Pozzecco, Francesco Salamone, Salvatore Sardo, Pasquale Severino, Maria Teresa Simoneti, Rita Zafonte.

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