



Original Research

Diagnostic values of glycated haemoglobin and diagnosis of diabetes: Results of a cross-sectional survey among general practitioners in the province of Reggio Emilia, Italy



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ABSTRACT

Aims: The aim of this study was to investigate whether subjects included in the diabetes register solely because their HbA1c was over the diagnostic threshold received a diagnosis of diabetes from their general practitioner (GP).

Methods: The study included all registered cases in 2009–2010 aged 18 or over that were identified only by the laboratory database because they had one or more HbA1c over the 6.5% threshold and for whom we did not find any information in the search of full electronic clinical records. Multilevel logistic regression was used to examine the influence of GP and patient characteristics.

Results: There were 228 participating GPs (76.3% of those invited) and 832 assessed subjects (68.8% of study population). There was a strong clustering among the GPs (residual intraclass correlation = 0.52, 95% CI 0.40–0.64). About one in two (55.5%) subjects with two or more HbA1c >=6.5% has been diagnosed as diabetic and the percentage declined – unless zeroing – in case the abnormal value was only one (28.3%). The likelihood of being labelled ‘no diabetes’ was greater in subjects aged less than 65 or over 74 with respect to the reference age group (OR 1.89, 95% CI 1.13–3.15; OR 1.55 95% CI 0.94–2.53). The same likelihood consistently decreased when HbA1c test was accompanied by abnormal fasting plasma glucose (FPG) assay (OR 0.20, 95% CI 0.12–0.32).

Conclusions: A permanent exchange of information between the diabetes register and GPs should be maintained to improve the care of patients and the awareness of criteria for diabetes diagnosis among GPs.

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Introduction

The onset of type 2 diabetes (T2DM) is slow, and the disease is often asymptomatic for a long time, as glucose levels increase only gradually over time. Diabetes may remain undetected for many years, thus leading to severe complications [1–4]. Therefore, diabetes must be diagnosed as early as possible, so that appropriate action can be taken to prevent or delay the development of complications. In 2011, a high level of glycated haemoglobin (HbA1c) was endorsed by the

World Health Organisation (WHO) as a sufficient criterion for T2DM using a diagnosis threshold of $\geq 6.5\%$ (48 mmol/mol) [5]. The WHO states that diagnosis can be based on either glucose tests or HbA1c, although in asymptomatic patients, elevated HbA1c or fasting glucose should be confirmed by repeating the same test [6].

The utility of HbA1c in diabetes screening is under discussion [7], especially because of its low sensitivity (42–44%), although its specificity is 99.6% [8].

Despite its low sensitivity, a threshold of 6.5% for HbA1c (48 mmol/mol) has a strong clinical rationale, since this is the level at which the risk of complications has been shown to rise and, indeed, at which measures should be taken to control glycaemia [6].

Given these considerations, the diabetes register for the province of Reggio Emilia includes the HbA1c measurement database

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among the sources, using 'having at least one HbA1c value of $\geq 6.5\%$ (48 mmol/mol) as an inclusion criterion' [9].

The aim of this study was to investigate whether the subjects included in the diabetes register solely because they have an HbA1c over the threshold did in fact receive a diagnosis of diabetes from their general practitioner (GP).

Material and methods

Setting

The diabetes register catchment area is the province of Reggio Emilia, which is situated in Northern Italy and has a population of approx. 550,000. It includes all resident patients who are identified by one or more of the following sources: hospital discharge, drug dispensation, HbA1c values from the biochemistry laboratory, disease-specific exemption, diabetes outpatient clinics, and mortality databases [9]. Women with gestational diabetes or who were receiving treatment for polycystic ovarian syndrome are excluded from the register. Furthermore, the applied algorithm is able to ascertain cases and to distinguish types of diabetes and care settings. Currently, the diabetes register contains both incident and prevalent cases of diabetes from 2009 to 2013.

For patients identified by one or more sources that do not specify the type of diabetes, full electronic clinical records are searched to complete the records. As per other disease registers based on routinely collected databases, the data collection and search in the electronic clinical record are delayed with respect to the reference period, and for the 2009–2010 data, both procedures were carried out during 2013. Once the uploading process is finished, a small group of subjects belongs to the register solely because they have of one or more HbA1c values over the threshold; these subjects are the population included in this study.

In accordance with regional guidelines [10], patients first see their GP and, if diabetes is suspected on the strength of glycaemic tests, they should be referred by the GP to diabetes clinics (DCs) to confirm the diagnosis and stage their diabetes. The patients included in this study were unknown to the DCs; therefore, they were not referred to specialised clinics for the initial assessment and are not included in any structured diagnostic and therapeutic pathway. Possibly, they could be diagnosed as T2DM and cared exclusively by their GP through diet and lifestyle advice, or they could be undiagnosed or they could have one abnormal HbA1c value due to being affected by pre-diabetes or by one of other conditions artificially increasing HbA1c values, carbamylated haemoglobin (renal failure), hypertriglyceridaemia, hyperbilirubinaemia, or iron deficiency [6,11].

To better understand if these subjects were diagnosed as having diabetes or not, and if not why, a survey of GPs was carried out.

Study design

This was a cross-sectional study conducted by surveying GPs. The study included all registered cases in 2009–2010 aged 18 or over that were identified only by the laboratory database because they had one or more HbA1c over the 6.5% threshold and for whom we did not find any information in the search of full electronic clinical records (Fig. 1). For this group of cases, there is no mention of diabetes anywhere in the available electronic sources; therefore, to know if they received a diagnosis or not we had to ask to their GPs.

Each GP received a list of his/her patients showing the date(s) and the value(s) of HbA1c assay(s), along with additional information about the fasting plasma glucose (FPG) assay, if this test was performed. The survey was conducted in the first six months of 2014;

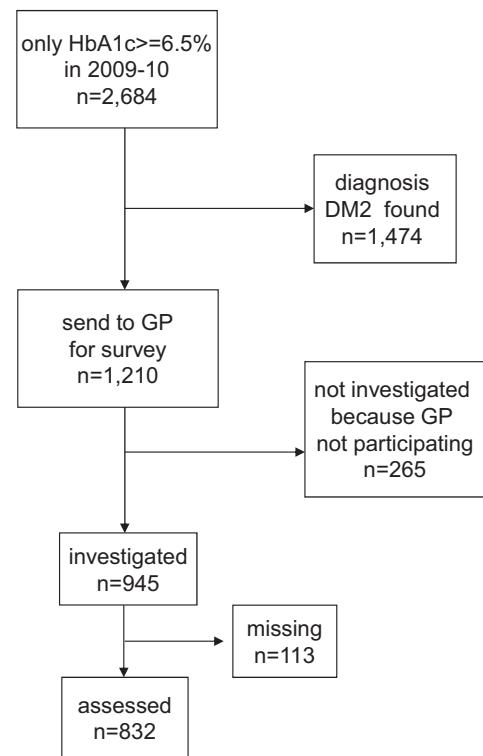


Figure 1. Study population selection flow.

hence, allowing the GP to answer according to the medical charts updates in 2014.

Outcome and covariates

The outcome of interest was confirmation of diabetes diagnosis by the GP (yes or no).

Independent variables included in the analyses are listed below:

GP level: sex, age (years).

Patient level: sex, age (years), foreign status (determined as per citizenship), first HbA1c value equal or over the threshold, number of HbA1c assays, value of FPG closest to first diagnostic HbA1c, all measures performed in 2009–2010. Additionally, for patients with only one HbA1c value over the threshold in the reference period, we retrieved information about further HbA1c tests done in 2011–2013, and we classified this variable in three categories: "further HbA1c $\geq 6.5\%$ in 2011–13"; "further HbA1c $< 6.5\%$ in 2011–13"; "not retested in 2011–13".

Statistical methods

We compared the demographic and clinical characteristics of the study population, stratified based on whether the GP answered or not. Afterwards, the subjects for whom a response was obtained were stratified by type of response. Chi square tests were performed to highlight possible differences in the probability to be assessed and to be diagnosed among the different categories of each of the considered variables.

Multilevel logistic regression was used to examine the influence of GP (level 2) and patient (level 1) characteristics on GP diagnosis in the assessed patients and separately in subjects with two or more HbA1c and in those not retested. The fixed effects are presented as odds ratios (ORs) with 95% confidence intervals (95%

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