ENDOCRINOLOGÍA Y NUTRICIÓN

ORIGINAL ARTICLE

An evaluation of glycosylated hemoglobin requesting patterns in a primary care setting: a pilot experience in the Valencian Community (Spain)

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Abstract

Objective: To assess the pattern of glycosylated hemoglobin (HbA$_{1c}$) requests by clinicians from eight health care departments by calculating indicators of demand appropriateness.

Methods: A cross-sectional study of the number of HbA$_{1c}$ requests by primary care clinics in 2008 and 2009. The indicator of demand appropriateness was the proportion of HbA$_{1c}$ values lower than 6.5%. Variables were collected and indicators were automatically calculated. The number of HbA$_{1c}$ measurements that should theoretically have been requested according to known diabetes prevalence data was also calculated.

Results: A progressive increase was seen in the demand for HbA$_{1c}$ measurements. Approximately 54% of HbA$_{1c}$ values obtained in seven of the eight departments studied were lower than 6.5%. The number of theoretical HbA$_{1c}$ requests that would have been expected based on the known prevalence of diabetes was higher than the number of HbA$_{1c}$ requests in all departments.

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Conclusion: The results appear to suggest that HbA$_{1c}$ requests in the health care departments studied were not always appropriate. HbA$_{1c}$ measurements were probably overused in patients without diabetes and underused in patients with diabetes.

Evaluación del patrón de solicitud de hemoglobina glucosilada por Atención Primaria: estudio piloto regional en la Comunidad Valenciana

Resumen

Objetivo: Mostrar el patrón de solicitud de hemoglobina glucosilada (HbA$_{1c}$) en ocho departamentos de salud mediante el cálculo de indicadores de adecuación de la demanda.

Métodos: Estudio transversal en el que se recogen el número de HbA$_{1c}$ solicitadas desde Atención Primaria durante los años 2008 y 2009. Como indicador de adecuación se calculó el porcentaje de valores de HbA$_{1c}$ con resultado inferior a 6,5%. Las variables y los indicadores se recogieron y calcularon de forma automatizada. También se calculó en cada departamento de salud el número de determinaciones de HbA$_{1c}$ teóricas que deberían haber sido solicitadas según datos de prevalencia conocida.

Resultados: Se observó un incremento progresivo de la demanda de determinaciones de HbA$_{1c}$ y, aproximadamente el 54% de los valores de HbA$_{1c}$ en siete de estos ocho departamentos fueron inferiores a 6,5%. El número de HbA$_{1c}$ teóricas que deberían haber sido solicitadas según la prevalencia de diabetes fue mayor que el número solicitado en todos los departamentos.

Conclusión: Los resultados parecen indicar la inadecuación en la solicitud de la HbA$_{1c}$ en los departamentos de salud estudiados, no sólo por la probable sobreutilización en pacientes no diabéticos sino por la infrautilización en pacientes que sí lo son.

Introduction

Type 2 diabetes mellitus (DM) is a chronic disease with a very high prevalence. Glycosylated hemoglobin (HbA$_{1c}$) values reflect blood glucose concentration during the 2-3 months prior to analysis. For the past 30 years HbA$_{1c}$ has been an essential marker when monitoring diabetic patients in order to prevent complications of the disease[1-3]. There is however evidence that the test is being inappropriately used in clinical practice[4].

A recent recommendation that HbA$_{1c}$ be used not only for the control of diabetic patients, but also for the diagnosis of diabetes[5,6] represents a significant change in the management of the test and will require new requesting patterns to be established. The International Expert Committee (IEC) has concluded that advances in instrumentation and standardization have made HbA$_{1c}$ tests as least as exact and accurate as those of glucose. In addition, the lower intraindividual and preanalytical biological variability of HbA$_{1c}$ as compared to plasma glucose and the fact that fasting is not required before blood collection supports the use of the test for disease diagnosis[5], which should lead to new approaches regarding its use.

Given the new diagnostic value of the biochemical variables[7], the first step must be to analyze the current HbA$_{1c}$ requesting patterns as a basis for establishing future demand for the test. A comparison of the tests requested by different health care areas or departments is considered a good approach because it can tell us the existing variability, and so help us establish the best clinical practice. In our case, the study objective was to assess the HbA$_{1c}$ requesting patterns of primary care (PC) physicians from eight health care areas.

Materials and methods

A cross-sectional study was conducted by assessing and analyzing HbA$_{1c}$ requests made during 2008 and 2009 by PC physicians in eight health care areas, each having a reference hospital with its own laboratory, caring for 31% of the population covered by the Valencian Health Authority (AVS).

To set up a network of participating laboratories, two surveys were sent to 13 laboratories in the AVS. Study inclusion criteria were the availability of the same laboratory computer system (SIL, Omega, Roche Diagnostic®) and a computer application based on a data warehouse and OLAP (on-line analytical processing) cubes (Omnium, Roche Diagnostic®), and the ability to stratify SIL results between clients (inpatient, PC, etc). Eight laboratories participated in the study. They tested samples from hospital departments and emergency rooms, and also from outpatient and PC clinics which were taken at the different health care centers and transported to the laboratory. Table 1 shows the population served by each health care department.

In a second stage, records and indicators were defined, agreed, and validated, and a common database was set up. An independent technician was selected to collect records and indicators from each laboratory and send them for analysis to Hospital de San Juan, the project coordinating center.

Table 1 Population served by each health care department. Number of HbA$_{1c}$ tests requested by PC and percentage of measurements with values lower than 6.5 in 2008 and 2009, and theoretical number of HbA$_{1c}$ measurements that should have been requested based on the American Diabetes Association (ADA) recommendations for control of diabetic patients

Department	Population served	HbA$_{1c}$ requested		% HbA$_{1c}$ with values < 6.5%		HbA$_{1c}$ tests required according to ADA[a]
		2008	2009	2008	2009	
A	197,029	18,574	21,325	48.5	43.21	22,600
B	254,233	24,346	21,719	54.59	53.07	29,161
C	274,233	14,663	18,098	65.10	48.83	31,455
D	271,218	21,258	22,519	54.79	55.95	31,110
E	55,282	4,836	5,455	48.83	53.16	6,341
F	372,138	ND	20,705	ND	28.14	42,686
G	357,267	ND	33,776	ND	60.57	40,980
H	233,075	14,458	18,641	54.61	66.00	26,735

ADA: American Diabetes Association; PC: primary care; HbA$_{1c}$: glycosylated hemoglobin.
[a]Number of measurements that should have been requested based on census, known prevalence of type 2 DM, and 2009 ADA recommendations.

HbA$_{1c}$ requests were assessed from January 2008 to December 2009 (2009 data were only included for two health care departments). To measure HbA$_{1c}$, all participating laboratories used a method certified by the National Glycohemoglobin Standardization Program (NGSP) which was not changed during the study period[8].

A threshold HbA$_{1c}$ value of 6.5% was established after discussion with specialists in endocrinology and nutrition, and any requests leading to a lower value were considered to be potentially inappropriate. Therefore, the proportion of all HbA$_{1c}$ measurements requested for patients controlled by PC giving values < 6.5% was calculated monthly as an indicator of appropriateness. Daily SIL records (demographic data and HbA$_{1c}$ requests) and the proposed indicators were collected and calculated at each health care department.

The theoretical number of HbA$_{1c}$ requests that should have been made based on the American Diabetes Association (ADA) recommendations for the control of diabetic patients was calculated based on the prevalence of type 2 DM in people aged over 18 years in the Region of Valencia[9] and on census data.

Results

Table 1 shows the number of HbA$_{1c}$ measurements requested by PC physicians from each health care department in 2008-2009, as well as the proportion of HbA$_{1c}$ values lower than 6.5% in the same period. A higher HbA$_{1c}$ demand was seen in 2009 in all health care departments except for department B. Variability was found between departments in the indicator of appropriateness, with center F showing a much lower mean as compared to all others. The data demonstrated that a value lower than 6.5% was found in approximately 54% of all HbA$_{1c}$ measurements requested from PC to seven laboratories in the Region of Valencia.

Figure 1 shows the monthly percentages of HbA$_{1c}$ values lower than 6.5% at each health care department. Table 1 shows the theoretical number of HbA$_{1c}$ measurements that

should have been requested based on ADA recommendations and the prevalence of type 2 DM in the Region of Valencia. Fewer HbA$_{1c}$ measurements were requested by all health care departments than should theoretically have been requested according to the above theoretical calculation.

Discussion

DM diagnostic criteria have recently been modified due to the standardization of the HbA$_{1c}$ measuring method and its correlation with the risk of occurrence of late complications of DM[5]. The cut-off point diagnostic of DM has thus been established at a HbA$_{1c}$ value ≥ 6.5%, and patients with HbA$_{1c}$ values ranging from 5.7%-6.6% have been defined as a group at high risk of developing DM[10,11]. New diagnostic criteria will possibly have a relevant impact on requests for the test to clinical laboratories, and the current situation should be analyzed at each health center to assume and predict the work load that may result from the new ADA recommendations.

The main limitations of this study were that clinical patient data were not available and HbA$_{1c}$ management in the monitoring of gestational diabetes was not considered. The results showed a greater demand for the test in PC in 2009 as compared to 2008 in all health departments but one. This increase was also reported by other studies, which additionally noted that this measurement was also requested for non-diabetic people at a time prior to the new indication for the test[12,13].

It should be noted that the study not only showed an increase in the number of HbA$_{1c}$ requests, but also a high proportion of patients with HbA$_{1c}$ values < 6.5% found at a time when HbA$_{1c}$ was not recommended for diagnosis (2008 and first six months of 2009). These data may suggest an **excellent DM control in PC or an inappropriate demand in** non-diabetic patients. However, the proportion of patients with HbA$_{1c}$ values < 6.5% differed between the health care departments. This data also suggests differences in the
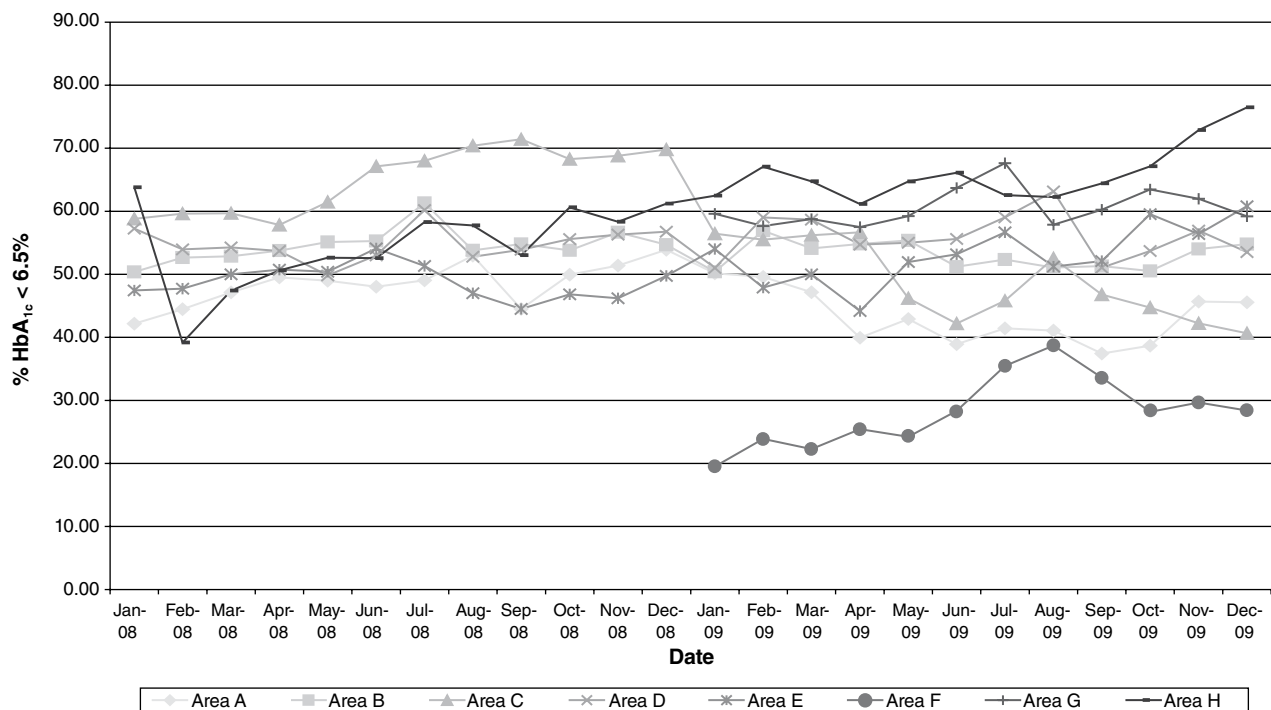
Figure 1 Monthly percentages of glycosylated hemoglobin values lower than 6.5% (b) at each of the eight health care departments of the study.

request patterns of this parameter, as DM prevalence was similar in all centers.

The increased number of requests for HbA$_{1c}$ measurement by PC physicians after July 2009 and the increased number of HbA$_{1c}$ values lower than 6.5% could be explained by the new indication of the test for DM diagnosis. However, such increase was progressive and did not only occur in the last half of 2009.

In recent years, in addition to an increased number of HbA$_{1c}$ requests for non-diabetic patients, inadequate use of the test has also been reported, consisting of non-compliance with DM guidelines for the number of requests required for adequate DM monitoring[14]. The prevalence of type 2 DM in subjects over 18 years of age in the Region of Valencia is 13.3%. Of these, 7.05% have known DM and 6.25% unknown DM[9]. According to municipal census data, 81.3% of the population of the Region of Valencia is older than 18 years. If this data is applied to the studied population (2,014,475 inhabitants), there are 1,638,775 inhabitants older than 18 years, of whom 115,534 would theoretically be known diabetics. The ADA recommends six-monthly assessment of HbA$_{1c}$ in patients with stable, well-controlled DM. Thus, assuming that all patients with DM met the therapeutic goals, 231,068 HbA$_{1c}$ measurements should have been performed annually. However, a lower number of tests were requested (162,238). This statement is even more serious if the total number of HbA$_{1c}$ tests requested by PC for people probably having no DM with a HbA$_{1c}$ value < 6.5% is subtracted from that figure. A limitation to the latter statement would be the

consideration that a large number of diabetic patients were at therapeutic goals. However, it has been reported that the proportion of Spanish patients with type 2 DM and a HbA$_{1c}$ value ≤ 6.5% ranges from 18%-28%. Thus, considering the low number of annual HbA$_{1c}$ measurements, far from the recommended number, most measurements yielding values < 6.5% were probably requested for non-diabetic people[15]. Nevertheless, another work group using data from a single primary care center applying the DM management guidelines, also in Spain, achieved HbA$_{1c}$ values lower than 7% in 54.8% of its patients[16].

The study results appear to suggest an inappropriate request for HbA$_{1c}$ measurements in this population, not only because they were probably overused in non-diabetic patients, but also because they were underused in patients with DM. New diagnostic criteria for DM will change the HbA$_{1c}$ requesting habits of PC physicians, and measurement indications and intervals should be left clear. DM screening is currently recommended for all people over 45 years of age with no risk factors for diabetes, and should be repeated every three years if a normal test is found. Screening age is earlier in adults with risk factors for diabetes[17].

Cooperation between endocrinologists, primary care physicians, and clinical laboratory professionals will be required to establish and implement request protocols and guidelines. Subsequent assessment of the request pattern using indicators of demand appropriateness such as those shown in the study will also be required to maintain an appropriate level of request for the test and thus resolve any potential deviation.

Conflict of interest

The authors state that they have no conflict of interest.

Acknowledgement

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