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An Evaluation of Hemoglobin A_{1c} Test Ordering Patterns in a Primary Care Setting

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Clinical History

Background: To evaluate the hemoglobin A_{1c} (HbA_{1c}) prescription patterns by primary care physicians before the International Expert Committee (IEC) guidelines and how they have changed.

Materials and Methods: The number of HbA_{1c} tests ordered from January 2002 to December 2009 was examined in a cross-sectional study. The percentage of HbA_{1c} results <6% and <5.5% were calculated. These cutoffs were decided after consultation of the literature regarding HbA_{1c} values that were unlikely to have diabetic patients. Repeat HbA_{1c} orders per patient were also tabulated.

Results: 95,321 HbA_{1c} tests were ordered. The percentage of HbA_{1c} results <6% and <5.5%, respectively, were 36.2% and 13.8%. The percentage of HbA_{1c} tests ordered with a result of <6% differed significantly between January 2009 to July 2009 and August 2009 to December 2009 (picked specifically because of the timing of the IEC guideline). Only 16% of patients had repeat HbA_{1c} tests in 2009.

Conclusions: It is necessary to conduct studies of HbA_{1c} testing patterns in order to establish corrective measures to ensure proper use of the tests.

Keywords: biological markers; efficiency and cost analysis; Type 2 diabetes mellitus.

Type 2 diabetes mellitus is a chronic illness with a relatively high prevalence, and glycemic control has been fundamental for the management of the disease. Hemoglobin glycation was first used 30 years ago to assess glycemia in subjects with type 2 diabetes mellitus. Since then, the hemoglobin A_{1c} (HbA_{1c}) assay has been the standard laboratory marker of glucose control and correlates well with long-term diabetes complications.[1,2] Hemoglobin A_{1c} is now a commonly used laboratory test for monitoring glycemia and managing type 2 diabetes mellitus.[3] However, there is compelling evidence that the test is used inappropriately in clinical practice.[4]

There is a growing interest in HbA_{1c} testing for a diabetes diagnosis.[5] The recent report by the International Expert Committee (IEC) on the diagnosis of type 2 diabetes mellitus[6] recommends the use of HbA_{1c} rather than glucose as a diagnostic criterion of diabetes. This report involves an important increase in the number of HbA_{1c} determinations.[7] The IEC concluded that advances in instrumentation and standardization make the accuracy and precision of an HbA_{1c} assay at least as good as those of glucose assays. Other advantages of HbA_{1c}, including low pre-analytical and biological variation, values reflecting long-term glycemia exposure, and no need for pre-test fasting, support this recommendation. In July 2009, the IEC determined that an HbA_{1c} value of 6.5% or greater should be used to diagnose type 2 diabetes mellitus.[6] The diagnosis should be confirmed by repeating the HbA_{1c} measurement on a different day unless clinical symptoms and glucose values >11.1 mmol/L (200 mg/dl) are both present. Hemoglobin A_{1c} concentrations of 5.7%-6.4% indicate individuals at high risk of developing type 2 diabetes mellitus. Repeat HbA_{1c} testing is not required for persons with results in this range.[8] Clinical laboratory professionals will have a vital role in implementing ordering procedures in conjunction with clinicians.

The objective of this study is to evaluate the HbA_{1c} prescription patterns by primary care physicians before the IEC guidelines and how they have changed after the guidelines were published.

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Abbreviations

IEC, International Expert Committee; HbA1C, hemoglobin A_{1c}; NGSP, National Glycohemoglobin Standardization Program; CE-HPLC, cation-exchange high-performance liquid chromatography; LIS, laboratory information system; ADA, American Diabetes Association

Materials and Methods

A cross-sectional study was made on the number of HbA_{1c} tests ordered by general practitioners from January 2002 to December 2009 in a health district of Alicante, Spain. This area holds 10 primary care centers where general practitioners can order tests without having to refer the patient to the main hos-

pital (San Juan Hospital), which serves a population of 234,424 inhabitants. The 10 different primary care centers included in the study used similar order forms for laboratory tests during the study period, until May 2009, when an electronic ordering system was implemented in primary care centers. All of these tests were usually carried out in the Clinical Laboratory Department of this hospital. The method used to measure HbA_{1c} was the National Glycohemoglobin Standardization Program (NGSP)-certified method;[9] cation-exchange high-performance liquid chromatography (CE-HPLC) (HbA_{1c} Program on the VARIANT II TURBO Link System, Bio-Rad Laboratories, Berkeley, CA), and there were no changes during the study period.

The study is based on an analysis of data collected from a laboratory information system (LIS). Hemoglobin A_{1c} testing was the primary outcome. To assess the rate of inappropriate test orders, laboratory records of the HbA_{1c} tests ordered between January 2002 and December 2009 were evaluated. After consulting the literature regarding HbA_{1c} values that were unlikely to have diabetic patients,[6] a <6% HbA_{1c} result was decided. Prior to the July 2009 guidelines and HbA_{1c} testing only for diabetic patient management, the possible inappropriate HbA_{1c} request was considered as any order for a given patient with an HbA_{1c} value result of <6%.

We examined HbA_{1c} test-ordering activity at 10 primary care centers to ascertain variations in ordering practice.

As defined above, a possible inappropriate HbA_{1c} request was considered as any order for a given patient with an HbA_{1c} result of <6%. Two suitability indicators were calculated for HbA_{1c} orders: 1) percentage of HbA_{1c} with a result of <6% and <5.5% regarding the total HbA_{1c} requested; and 2) the number of repeat HbA_{1c} determinations ordered per patient with a result of <6% and the number of repeat orders per patients with a result of >6.5% in 2008 and 2009. The first parameters, HbA_{1c} with a result of <6 % and <5.5%, were used to ascertain inappropriate HbA_{1c} due to probable use in nondiabetic patients and the second, the number of repeat HbA_{1c} determinations ordered per patient with a result of <6% and >6.5%, were used to estimate compliance with recommendations for use in type 2 diabetic patients (ie, inappropriate use of the test due to the non-repetition of the test in type 2 diabetic patients in a 1-year period).

We collected the total HbA_{1c} orders and the percentage of HbA_{1c} results <6% and <5.5% regarding the total number of HbA_{1c} ordered for patients managed by general practitioners in each primary care center for every annual period. The same results were assessed from January 2009 to July 2009 (before the IEC recommendations) and from August 2009 to December 2009 (after the new diagnostic HbA_{1c} indication was implemented), and in the same periods in the remaining years of the study. The number of HbA_{1c} tests per patient every year was also collected to confirm recommendations for type 2 diabetes mellitus control were being followed. We calculated the percentage of HbA_{1c} orders with respect to the total number of primary care orders in these periods to highlight the increase in HbA_{1c} orders with respect to total orders.

Differences in HbA_{1c} testing between periods and between the 10 primary care centers were tested with the Chi-square test using SPSS software (Chicago, IL).

Results

A total of 95,321 HbA_{1c} tests (patients more than 18 years old, 50,520 women and 44,801 men) were ordered by general practitioners during the study period (January 2002-December 2009). The annual percentage of HbA_{1c} orders regarding the total orders is shown in **Figure 1**. If we focus only on 2009, the percentage increases significantly in the second half of the year. This percentage is 18.97% for February 2009 to April 2009, 20% for May 2009 to July 2009, and 22.51% for August 2009 to October 2009. The differences between the first and third period and between the second and third period were significant (P<0.001 and P=0.003, respectively).

The percentage of HbA_{1c} with results of <6% and <5.5% regarding the total HbA_{1c} requested by general practitioners were 34,548 (36.2%) and 13,163 (13.8%). The same results are broken down annually in **Figure 2**. In the January 2002 to July 2009 and August 2009 to December 2009 periods, an HbA_{1c} result <6% was found in 35.71% and 42.15%, respectively. The percentage of HbA_{1c} with a result of <6% for the periods January to July and August to December in the different years of the study are shown in **Table 1**. Only in 2009

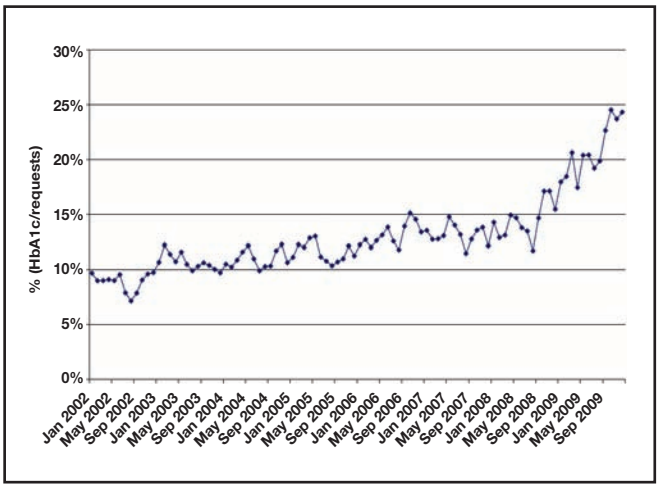
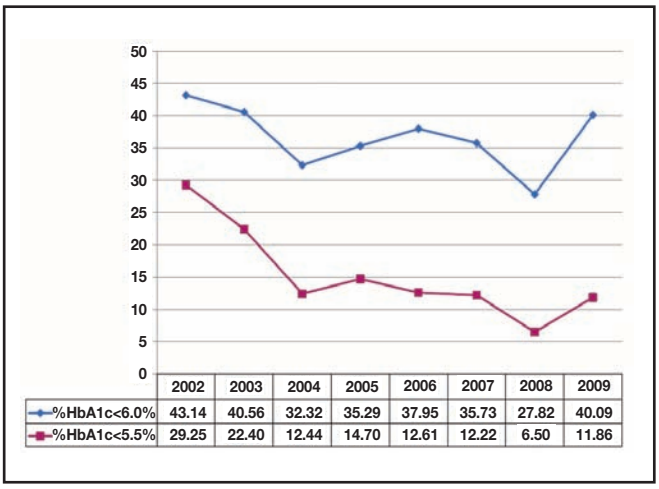


Figure 1_Percentage of HbA_{1c} requested from primary care centers to total requests. The figure shows the percentage of HbA_{1c} requested from primary care centers to total requests in the study period.



	2002	2003	2004	2005	2006	2007	2008	2009
%HbA1c<6.0%	43.14	40.56	32.32	35.29	37.95	35.73	27.82	40.09
%HbA1c<5.5%	29.25	22.40	12.44	14.70	12.61	12.22	6.50	11.86

Figure 2_Percentage of HbA_{1c} tests with the results of <6% and <5.5% for total requested HbA_{1c} ordered by general practitioners of Alicante every year during the study period. In 2009, the downward trend is reversed.

Table 1_Annual Comparison Between the Percentage of HbA_{1c} With Results Below 6% Regarding HbA_{1c} Total Orders in January to July and August to December Periods

	% HbA_{1c} <6%		
Year	Jan-Jul	Aug-Dec	*P* Value
2002	43.61%	43.58%	0.97
2003	44.94%	43.76%	0326
2004	33.34%	33.29%	0.96
2005	37.19%	36.34%	0.37
2006	39.93%	40.81%	0.41
2007	36.37%	36.35%	0.98
2008	26.48%	26.75%	0.71
2009	38.59%	42.15%	<0.001

was the difference between the 2 periods statistically significant (P<0.001).

The percentage of HbA_{1c} tests with results of <6% and <5.5% regarding the total HbA_{1c} requested annually by each primary care center is shown in **Table 2**. The annual differences between each center when compared with the mean group were statistically significant, as were the differences within the same center in 2008 and 2009 (P<0.001). In 2004 the dispersion between centers is greater in both HbA_{1c} <6% in <5.5%.

The number of HbA_{1c} tests with a result of <6% and >6.5% regarding the total HbA_{1c} ordered per patient in primary care centers in 2008 and 2009 is shown in **Table 3**. In a large number of patients, the HbA_{1c} test was ordered only once, including patients with HbA_{1c} <6% and patients with HbA_{1c} >6.5%. The difference between patients with HbA_{1c} <6% and patients with HbA_{1c} >6.5% who had only 1 HbA_{1c} test/year was significant (P<0.001). The percentage was lower in patients with diabetes (HbA_{1c} >6.5%). However, the percentage remains too high (76.56%) in 2009.

The prevalence of type 2 diabetes mellitus in the Autonomous Community of Valencia among subjects older than 18 years is 13.3%, of which 7.05% is known diabetes mellitus and 6.25% is unknown diabetes mellitus.[10] Consequently, our health district should have about 13,852 patients with diabetes. The ADA recommends measuring HbA_{1c} every 6 months in patients with stable and well-controlled diabetes mellitus. Assuming all patients with diabetes mellitus comply with therapeutic objectives, about 27,704 HbA_{1c} measurements should be made every year (according to data from the 2009 census); in reality, 18,665 samples were analyzed.

Discussion

The diagnostic criteria for type 2 diabetes mellitus were recently modified due to standardization of the HbA_{1c} determination method and the correlation of test results with the risk

Table 2_Percentage of HbA_{1c} Tests With a Result of <6% and <5.5% Ordered at Different Primary Care Centers in Each Year of the Study

A %HbA_{1c} <6%

Center	2002	2003	2004	2005	2006	2007	2008	2009
1	42.91	29.21	24.60	24.65	34.44	30.73	23.91	32.73
2	34.23	26.47	22.83	28.96	36.86	45.41	45.64	42.92
3	46.36	41.40	41.10	37.53	29.87	26.56	24.24	39.30
4	24.05	19.67	14.33	14.20	20.81	19.35	15.19	37.79
5	39.02	20,37	13.67	33.43	45.89	19.05	13.04	30.60
6	45.16	50.67	34.16	37.20	41.03	37.23	33.70	43.02
7	38.08	24.16	19.01	39.51	40.86	38.04	20.00	40.46
8	37.64	30.47	30.25	44.42	39.00	36.36	24.59	36.69
9	63.00	55.60	48.99	40.45	34.96	31.61	21.89	38.76
10	45.74	50.85	38. 22	36.76	41.43	44.02	38.65	42.46
Annual mean	41.62	34.89	28.72	33.71	36.52	32.84	26.09	38.47
SD	10.05	13.56	11.86	8.91	7.11	9.18	10.29	4.21
CV (%)	24.15	38.87	41.30	26.44	19.47	27.97	39.43	10.95

B %HbA_{1c} <5.5%

Center	2002	2003	2004	2005	2006	2007	2008	2009
1	27.68	13.01	7.93	8.79	12.26	9.08	4.41	9.22
2	16.63	13.24	6.74	8.96	11.96	15.46	7.67	13.46
3	32.77	23.84	17.04	13.89	9.41	7.18	5.76	11.74
4	11.73	8.85	3.86	4.35	6.36	4.99	2.85	10.64
5	25.25	10.19	3.91	14.33	19.07	7.14	2.61	10.85
6	30.66	27.82	13.67	15.02	12.66	11.73	8.06	13.19
7	19.49	10.6	5.1	12.59	13.65	13.94	5.17	12.45
8	21.88	11.96	8.25	15.23	11.00	9.54	5.71	10.27
9	53.75	33.52	20.92	14.35	10.77	10.89	4.63	10358
10	34.43	31.88	16.73	15.31	15.54	20.04	10.01	13.54
Annual mean	27.43	18.49	10.42	12.28	12.27	11.00	5.69	11.59
SD	11.75	9.69	6.17	3.69	3.43	4.50	2.33	1.51
CV	42.84	52.41	59.24	30.06	27.98	40.91	40.93	13.00

Table 2 shows the annual percentage of HbA_{1c} with a result lower than 6% and with a result lower than 5.5% in regards to the total HbA_{1c} tests in each center studied. The annual differences between centers (each 1 with the mean for the group) were statistically significant, as were the differences within the same center in 2008 and 2009 (P<0.001).

Table 3_Number of HbA_{1c} Tests With a Result of <6% and >6.5% Carried Out Per Person in 2008 and 2009

	2008		2009	
	Patients With HbA_{1c} <6%	Patients With HbA_{1c} >6.5%	Patients With HbA_{1c} <6%	Patients With HbA_{1c} >6.5%
All patients	4697	5873	8035	4924
1 HbA_{1c} per patient	4543 (96.72%)	5273 (89.78%)	7408 (92.20%)	3770 (76.56%)
2 HbA_{1c} per patient	148 (3.15%)	553 (9.42%)	576 (7.17%)	958 (19.46%)
3 HbA_{1c} per patient	6 (0.13%)	43 (0.73%)	51 (0.63%)	170 (3.45%)
4 HbA_{1c} per patient	0	4 (0.07%)	0	20 (0.41%)
5 HbA_{1c} per patient	0	0	0	5 (0.10%)
6 HbA_{1c} per patient	0	0	0	1 (0.02%)

The difference between patients with HbA_{1c} <6% and patients with HbA_{1c} >6.5% in which only 1 HbA_{1c} test ordered was significant (P<0.001). Although the percentage HbA_{1c} requested once is lower in patients with HbA_{1c} >6.5%, it is too high.

of developing diabetic complications.[6] The cutoff point for the diagnosis of diabetes mellitus is set at ≥6.5%, and a group of subjects at a high risk of developing diabetes mellitus is defined as those with HbA_{1c} results in the 5.7%-6.4% interval. The interest of this risk group is due to the observation that patients with HbA_{1c} within the 5.5%-6% range have an increased risk of developing diabetes mellitus in the upcoming years.[11,12] As the new diagnostic criteria can be expected to have an impact on the clinical analysis laboratory, we decided it would be useful to analyze the current situation at each work center in order to manage the workload and anticipate any increases the new recommendations by the American Diabetes Association (ADA) may generate.

Our study revealed an annual increase in the demand for HbA_{1c} tests in primary care. This was supported by a 3-fold increase in the number of HbA_{1c} tests processed from 2002 to 2009. This phenomenon has also been observed by other investigators, who also have reported that HbA_{1c} tests were often ordered for people who did not have diabetes[13,14] in the period before the new indications for the test were published.

It is interesting to note that not only did the number of HbA_{1c} test orders increase in our study, but there was also a larger number of patients with <6% and even <5.5% in a period in which diagnostic recommendations regarding the use of HbA_{1c} had not been clearly formulated. The bulk of the workload related to diabetic patient care weighs heavily on primary care physicians. The findings of our study suggest either an excellent control of diabetes mellitus in primary care or inappropriate orders for patients who do not have diabetes. The percentage of people with HbA_{1c} <6% and <5.5% differed between primary care centers in our work area. This indicates differences existed in the pattern of HbA_{1c} orders, since the prevalence of diabetes mellitus is similar at all the centers.

The increase in the number of HbA_{1c} tests ordered by primary care physicians since July 2009 and the increase in the percentages of these with results lower than 6% or 5.5% could be attributed to the new indication for HbA_{1c} tests in the diagnosis of diabetes, although this indication was not formulated in ADA recommendations until January 2010.[8] In order to clarify this point, we compared the number of HbA_{1c} results below 6% and 5.5% regarding total ordered HbA_{1c} in the period from August 1, 2009, until the end of 2009 with the January 2009 to July 2009 period. A significant difference was found between these 2 periods. This finding indicates that there were a larger number of test orders for patients who did not have diabetes. This increase was associated with the implementation of an electronic order system in primary care centers (May 2009). The short time available for patient visits and the complexity of the electronic laboratory order model predisposed physicians to choose profiles not specific for diabetes. This increase could also be explained by the implementation of a diabetes profile among the other profiles. The diabetes profile includes HbA_{1c} and may be used for subjects without diabetes, thus aggravating the problem of inappropriate HbA_{1c} orders. It has been demonstrated that the most frequent error when ordering laboratory tests is to add unnecessary tests.[15] However, direct electronic orders may be a cost-effective practice for adjusting demand, particularly if general practitioners are properly trained and suitable decision-making protocols are used.[16] In recent years, in addition to reporting an increase in the number of HbA_{1c} tests ordered for patients who do not have diabetes, there has also been an inappropriate use of HbA_{1c} noncompliant with test-ordering guidelines for optimal diabetes control.[17] One limitation of our study is that we could not establish the diagnosis of diabetes mellitus in patients in which HbA_{1c} was determined because we did not have this information in the laboratory database. What is clear, however, is that patients with HbA_{1c} >6.5% are diabetic. For that reason, we can assess the adequacy of the HbA_{1c} test in this group by evaluating the number of times in a year the test was performed and its relation to the number of individuals with diabetes in our population. In view of the number of times per year the HbA_{1c} test is repeated, it is clear that a large percentage of these patients have the test only once a year. This finding reflects the scant number of HbA_{1c} tests ordered for the diabetes mellitus follow-up. This finding is even more serious if we subtract the percentage of patients who probably do not have diabetes (HbA_{1c} <6%) from the total number of HbA_{1c} tests ordered by primary care. One caveat to this last statement might be that a large number of patients with diabetes could be within therapeutic range. However, it has been reported that the percentage of patients with type 2 diabetes and HbA_{1c} ≤6.5% is in the range of 18%-28%. Consequently, considering the small number of annual HbA_{1c} determinations, much lower than recommended, the majority of determinations with a result of <6% most likely correspond to persons without diabetes.[18] In any case, another working group, using data from a single primary care center in which diabetes mellitus management guides are applied, has been able to achieve HbA_{1c} <7% in 54.8% of patients.[19]

Therefore, one noteworthy problem disclosed is the inappropriate use of HbA_{1c} tests given the small number performed on patients with diabetes mellitus and the likelihood of overuse in patients who do not have diabetes.

New diagnostic criteria of diabetes mellitus will change HbA_{1c} test habits of primary care physicians. Moreover, the indications for HbA_{1c} testing and test periodicity should be made more clear. At the present time, screening for diabetes mellitus is advised in everyone over age 45, whether or not they have risk factors for the development of diabetes. If the test result is normal, the test should be repeated every 3 years. The age for screening is younger in adults with diabetes risk factors.[20] Patients with HbA_{1c} results between 5.7% and 6.4% should be tested more frequently.

Two determinations of HbA_{1c} every year are recommended for diabetic patients with good glucose control. However, an HbA_{1c} determination every 3 months is recommended for diabetic patients with poor glucose control or when significant changes in the therapeutic scheme are made.

If a first HbA_{1c} determination is normal, it should be repeated in 3 years, because of progressive risk of developing diabetes with age.[21]

Conclusion

This study has shown it is necessary to conduct studies of HbA_{1c} testing patterns in health districts in order to collect and analyze data and establish corrective measures to ensure proper use of the tests. The key to achieving this goal is interdepartmental cooperation between endocrinologists and primary care and laboratory professionals to develop protocols and guidelines and put them into practice. It is also necessary to evaluate test-ordering patterns by examining indicators of the appropriateness of demand in order to adhere to guidelines for ordering the test and to correct possible deviations. Such studies are crucial, particularly given the current imperious need to optimize efficiency in medicine. LM

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