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Interest and limits of HbA1c in Management of Diabetes Mellitus

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Abstract

Correct glycemic control, assessed by the glycated hemoglobin level, is necessary to prevent chronic complications of diabetes mellitus, the progression of which is alarming throughout the world.

**Aim:** The aim of this work is to evaluate the glycemic control of Gabonese diabetic patients followed externally at the university hospital of Libreville and discuss about the value of HbA1c in our context.

**Patients and methods:** we performed a cross-sectional prospective study based on data brought back by outpatients during their periodic controls between October and November 2016.

**Results:** 200 patients had been registered and 160 (80%) had done their HbA1c test, among which 63 % of women and 37 % of men. Average HbA1c was 7.74 ± 2.24%. 46.25% had an HbA1c rate ≤ 7%, 18.75% between 7.1% and 8%, and 35% over 8%. Oral antidiabetic drugs were prescribed in 68.12% of patients, insulin alone in 14.37%, and the combination of insulin and oral antidiabetic drugs in 11.87% of patients.

**Conclusion:** These results are encouraging in African context but their interpretation must be qualified because of the high prevalence of hemoglobinopathies, anemia and G6PD deficiency, which distort the glycated haemoglobin assay.

**Keywords:** HbA1c, Limits, Interest, Africa, Gabon

Introduction

Diabetes mellitus, which affects approximately 425 million people worldwide [1], owes its seriousness to its complications: acute, metabolic and chronic, degenerative. Famous previous epidemiological studies [2,3], have shown the interest of the glycated hemoglobin (HbA1c) level as a biological marker predicting the occurrence of these chronic complications. Thus, the HbA1c level, reflecting mean of last three months glycaemia, is considered as the gold standard for assessing the quality of diabetic monitoring [4,5] and since 2009, it is also recommended for diabetes screening [6]. However, many pitfalls must be taken into account when interpreting HbA1c levels both as a diagnostic criterion and for monitoring diabetic patients [7,8]. Indeed, racial differences have been noted in HbA1c levels in USA for many reasons [5] and various pathological situations distort HbA1c measurement [4,7]. According to the guidelines of academic societies [9,10], we must try to obtain an HbA1c level ≤ 7% for the majority of patients. For those whose diabetes has just been discovered and who do not have co-morbidities, a rate ≤ 6.5% can be
targeted, nevertheless a too strict objective has been correlated with a higher mortality [11]. For older patients and / or with co-morbidities, rates of 8% or even 9% can be accepted. In Gabon, where the prevalence of diabetes mellitus is about 7%, according to the latest IDF estimates [1], no study evaluating diabetic patients follow-up have not yet been done. The aim of this research is to evaluate the quality of glycemic control of Gabonese diabetics externally followed at the University Hospital Center of Libreville (CHUL), a reference center for Diabetes in Gabon where the National Health Insurance and Social Security Fund (CNAMGS) covers health expenditure for 80%. So, the HbA1c test only costs 2500 Francs CFA (4.5 US$) in public structures. Through this research we also want to point out interest and limits of HbA1c in our African context.

Materials and Methods

We undertook a cross-sectional prospective study at the CHUL in October- November 2016 to evaluate the quality of glycemic control of patients by the measurement of HbA1c. It was not a new experimentation, we just noted HbA1c results of each patient coming for his periodic control. HbA1c test is requested once a quarter and in patients files we got information about age, sex, duration of diabetes, treatment followed, weight, height (calculation of body mass index BMI), blood pressure and history of hypertension. HbA1c assays had been done in various laboratories. The CHUL’ one, uses the High Performance Liquid Chromatography (HPLC) technique, which is considered the most reliable method in routine [8,12], but there is often shortage of reagents. Other private laboratories use immunological techniques of latex agglutination inhibition and immunochromatography rapid tests.

Statistical analysis was performed using SPSS, and R software and EXCEL for figures. Quantitative variables are presented as means ± Standard Deviation (SD) and qualitative parameters by numbers and percentage. Various tests examined correlations between HbA1c and other variables (sex, age, BMI, and duration of diabetes). Values of p <0.05 were considered statistically significant.

Results

200 patients were registered including 126 women (63%) and 74 men (37%), 40 patients (20%) did not complete their HbA1c test. The mean HbA1c level was 7.74% ± 2.24, the mean duration of diabetes was 7.14 ± 6.84, the mean age was 57.92 ± 12, 19 years and average BMI was 28.79 kg/m² ± 5.2. These results are reported in Table 1.

We classified the results of HbA1c into three groups reflecting the quality of control: values ≤ 7%, 74 (46.25%), those between 7.1 and 8%, 30 (18.75%) and values > 8%, 56 (35%). These results are reported in figure 1.

Table 1: Descriptive statistics of analyzed parameters.

<table>
<thead>
<tr>
<th>Variable</th>
<th>HbA1c</th>
<th>BMI (kg/m²)</th>
<th>Age (years)</th>
<th>Duration (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>7.74%</td>
<td>28.79</td>
<td>57.12</td>
<td>7.14</td>
</tr>
<tr>
<td>SD</td>
<td>2.14</td>
<td>5.2</td>
<td>12.19</td>
<td>6.84</td>
</tr>
<tr>
<td>Minimum</td>
<td>3%</td>
<td>18.9</td>
<td>21</td>
<td>0.1</td>
</tr>
<tr>
<td>Maximum</td>
<td>14.90%</td>
<td>48.12</td>
<td>91</td>
<td>36</td>
</tr>
</tbody>
</table>

Correlations’ analysis between the mean HbA1c level and various variables showed a significant difference with sex: Kruskal-Wallis test, p = 0.02738. No significant links were found with the other variables: mean age (Spearman’s rho = 0.082, p = 0.32), BMI (Spearman’s rho = 0.07, p = 0.39), mean duration (Spearman rho = 0.055 p = 0.50). This lack of correlation was found when these different variables were analyzed according to the three HbA1c levels (Table 2).

Table 2: Correlations between HbA1c and Age - BMI - duration of diabetes.

<table>
<thead>
<tr>
<th>Group1</th>
<th>Group2</th>
<th>Group3</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 7%</td>
<td>≥ 7.1% ≤ 8%</td>
<td>≥ 8.1%</td>
<td></td>
</tr>
<tr>
<td>Mean Age</td>
<td>59.35 ± 11.16</td>
<td>56.50 ± 9.27</td>
<td>56.79 ± 14.40</td>
</tr>
<tr>
<td>Mean duration</td>
<td>6.86 ± 6.79</td>
<td>8.73 ± 7.94</td>
<td>6.87 ± 7.07</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>29.15 ± 5.30</td>
<td>28.09 ± 4.51</td>
<td>29.40 ± 5.69</td>
</tr>
</tbody>
</table>
A prevalence of treated hypertension was found in 63% of patients.

Prescribed Treatment: Oral Antidiabetic Drugs (OAD): 109/160 (68.12%) Metformin alone 40 patients (25%), Sulfonylureas alone 8 (5%), IDPP4 alone 5 (1.87%), Glucosidase inhibitors alone 3 (1.87%). Association 2 OAD 52 (32.5%) Metformin + sulfamides 49 (30.62%). Association 3 OAD 6 (3.70%). Insulin alone 23 (14.37), insulin + OAD 19 (11.87).

Discussion

Good glycemic control (HbA1c ≤ 7%) was found in about 46% of Gabonese diabetic patients attending outpatients' clinic of the CHUL. Our results are very different from what is found in most sub-Saharan African countries where the situation is considered worrying [13]. Indeed in a Guinean study [13], only 5, 5% of patients had done their HbA1c test; the mean level of this HbA1c was 9.15%, compared to 7.7% in our series. In the Diabcare Africa Study [14], only 1/3 of the patients had reached the target and the average HbA1c was 8.2 ± 4%. In western countries, the 2007-2010 Entered study in metropolitan France and the overseas departments [15] showed an average HbA1c level of 7, 1% and 7.4%, respectively. 52, 1% of metropolitan patients had an HbA1c level <7% against 41, 7% overseas [16]. In USA, 52, 5% of diabetic patients had HbA1c < 7% [17] but afro Americans had worse results [18].

How can one explain the results of Gabon? Gabon is a small country and 2/3 of the population lives in Libreville, the capital, where the offer of care is diversified and the role of the CNAMGS which covers the care at 80% is undeniable. However, these results concern the urban environment and we do not know what is happening in rural areas. In our study there was more women than men and they had a better glycemic control (p = 0.027). This Female predominance has also been found in a multi-center African study [19] and in French overseas departments [16]. One could wonder why? Is it because of men's work or negligence? In the Entered study [16] the reason given is the greater propensity of women to seek medical help. There were no significant links between the mean level of HbA1c and the mean age and mean duration of the diabetes. Actually, poor compliance is more common among young people [19,20], but in our study, there were mainly adults with a mean age of 57 years. As for duration of diabetes, it is well known that it is negatively correlated with glycemic control [19]. We did not find this link, maybe by the great range of data from 1 month to 36 years of duration.

Nevertheless, there is hope with new generation devices to improve the HbA1c assay techniques [28] and with the work of the National Glycohemoglobin Standardization Program (NGSP) to improve standardization of HbA1c assays and limit interferences [29]. To overcome these difficulties, the American Diabetes Association (ADA) [9] suggests in these cases to rely more on Self-Monitoring Blood Glucose (SMBG). However, the best approach correlated with the HbA1c level is the continuous measurement of glucose [30] available in the West but not yet commonly used in our countries. Since this method does not use the usual devices measuring blood glucose, we suggest to recover them from western countries and redistribute them to sub-Saharan Africa, taking into account our continent will experience the greatest increase in diabetes in the coming years [1]. In spite of its limitations HbA1c keeps its interest as an appropriate test for monitoring diabetes in the majority of people of diverse genetic backgrounds [5], compared to fasting plasma glucose, with the ability...
to capture chronic hyperglycemia, and predict diabetes related complications [7].

**Conclusion**

Provided limits in HbA1c levels interpretation, about 46% of Gabonese diabetic patients followed at CHUL are at goal. Continuing medical education and patients’ therapeutic education could help to improve these results. Nevertheless we should take into account all the limitations of HbA1c assay in our context and rely not only on HbA1c but also on SMBG for monitoring of diabetic people.

**Disclosure of Interest**

MP Ntyonga-Pono invitation as speaker, Novartis Laboratories. Invitation as auditor in congresses: Servier Laboratories, Sanofi, Novo-Nordisk. Advisory member for Novo-Nordisk

M F. Gorra Invitation as auditor in congresses: Servier Laboratories, Sanofi, Novo-Nordisk

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P. Bilogue.: Invitation as auditor in congresses: Servier Laboratories, Sanofi, Novo-Nordisk

M. Barry. No competing interest

S. Nkoh-Ngoma. No competing interest

G. Ndongou. No competing interest

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