Differences in interpretation of haemoglobin A1c values among diabetes care professionals

E. Lentes-Westra1,2, R.K. Schindhelm3,4*, H.J.G. Bilo5,6, K.H. Groenier7,8, R.J. Slingerland1,2

Departments of 1Clinical Chemistry, 4Internal Medicine, Isala, Zwolle, the Netherlands, 2European Reference Laboratory for Glycohaemoglobin, Zwolle, the Netherlands, 3Department of Clinical Chemistry, Haematology & Immunology, Medical Centre Alkmaar, Alkmaar, the Netherlands, 5Department of Clinical Chemistry and Haematology, Gemini Hospital, Den Helder, the Netherlands, Departments of 4Internal Medicine, 8General Practice, University Medical Centre, Groningen, the Netherlands, 7Diabetes Kenniscentrum, Isala Klinieken, Zwolle, the Netherlands, *corresponding author: tel.: +31 (0)72-5484444, email: roger@schindhelm.nl

ABSTRACT

Background: To assess the expected precision of HbA1c measurements and the magnitude of HbA1c changes eliciting the advice to change treatment among diabetes care professionals.

Methods: A seven-item questionnaire was sent to participants through a website. The survey focused on physicians and nurses involved in diabetes care.

Results: In total, 104 physicians, 177 diabetes specialist nurses, and 248 primary care nurses responded to the survey. A large number of the nurses (44%) and only a small number of the physicians (4%) were not aware of the inherent uncertainty of HbA1c results. Nurses considered adjusting therapy based on very small changes in HbA1c whereas physicians in general adhere to 0.5% (5.5 mmol/mol) as a clinically meaningful cut-off point. After therapy adjustment, a very small (0.1%) or no increase in HbA1c was considered to be significant enough to conclude that glucose regulation has worsened by 49% of the nurses and only 13% of the physicians.

Conclusion: Significant differences exist in the interpretation of changes in HbA1c results between physicians and nurses. Nurses consider therapy changes based on very small changes in HbA1c whereas physicians preferably agree to the clinically relevant change of 0.5% (5.5 mmol/mol). Changing therapy based on relatively small changes in HbA1c might lead to undue adjustments in the treatment of patients with diabetes. There is a clear need for more training for all diabetes care professionals about both the clinical significance and accuracy of HbA1c measurements.

KEYWORDS

Glycated haemoglobin, interpretation, healthcare professionals, nurses, physicians

INTRODUCTION

Both in subjects with type 1 and type 2 diabetes mellitus, adequate glucose control is considered of major importance.1 The degree of glucose control can be assessed by frequent home blood glucose measurements, but the most widely acknowledged and reliable assessment is the measurement of the concentration of glycated haemoglobin (HbA1c).2 As such, HbA1c is one of the main parameters with regards to glucose control in most outcome studies.3,4 Therefore, most diabetes care professionals rely (at least in part) on HbA1c levels to decide whether or not to recommend treatment changes to patients.

Still, HbA1c measurement, and thus the interpretation of results, has its pitfalls. The analytical performance of the HbA1c assay is an important factor in the overall performance of the HbA1c assay.5,6 Not all laboratories may be able to measure HbA1c precisely enough to allow an outcome within 0.5% (5.5 mmol/mol) of the actual value.6 For example, in the Netherlands, initiation of insulin therapy would be considered in a person with type 2 diabetes mellitus with an HbA1c > 7.0% (53 mmol/mol) on maximal oral therapy, at least based on the advice in the 2006 primary care guideline which was the prevailing document at the time of this survey.7
Currently, limited data are available on how healthcare professionals perceive the accuracy of the HbA1c assay and how they adjust therapy based on consecutive changes in HbA1c. One study demonstrated that the majority of general practitioners presumed a high (analytical) performance of the assay without considering the biological variation, and acted on even small differences in subsequent HbA1c measurements. Studies assessing the difference between various healthcare professionals, including physicians and nurses, with respects to interpretation of (changes in) HbA1c, are lacking. The aim of this study was to assess the daily practice regarding the interpretation of HbA1c results, i.e. the expected precision of HbA1c, and the magnitude of HbA1c changes possibly eliciting the advice to change treatment. Therefore, we surveyed a group of diabetes care professionals regarding these aspects.

**MATERIALS AND METHODS**

**Design**

In this cross-sectional descriptive study, an internet survey was used to collect data. The study was part of a larger survey regarding the frequency of self-monitoring of blood glucose recommended by professionals and was carried out from March to June 2010. Respondents were asked to indicate their profession (physician, diabetes specialist nurse or primary care practice nurse, P, DSN and PCPN, respectively). The remainder of the questionnaire included six questions regarding the use and interpretation of HbA1c. The first question assessed the expected reliability of HbA1c at a level of 7.0% (53 mmol/mol). In the other five questions, patient cases were presented assessing at what HbA1c level or HbA1c changes the healthcare professional would initiate or change therapy (table 1). In total, 6965 primary care assistants, diabetes specialised nurses and doctors from the database of the Langerhans Medical Research Group were invited by email to participate in this survey. The Langerhans Medical Research Group is the research division of the Langerhans Foundation, a national diabetes organisation that organises educational activities for diabetes care professionals. The database contains information and a small number of the physicians (4%) were not aware of the inherent uncertainty of the HbA1c result. When comparing the responses of the two groups of nurses, they were not significantly different from each other (p = 0.714, Bonferroni corrected). The responses to Case B (table 1B, figure 1B) show that a cut-off point of 7.0% (53 mmol/mol) is regarded as a signal for treatment changes by 19.8% of the healthcare professionals regarding these aspects.

**Statistical analysis**

Differences in the distribution of answers between the groups (P, DSN and PCPN, respectively) were tested using Fisher’s exact test. P-values < 0.05 were considered statistically significant. Comparisons between pairs of groups were adjusted for multiple testing using the Bonferroni correction. SPSS version 20 (IBM Corporation, Armonk, NY) was used for the analysis.

**RESULTS**

For this analysis, 529 healthcare professionals were included: 48 internists, 28 general practitioners, 28 paediatricians (total physicians = 104), 177 diabetes specialist nurses and 248 primary care practice nurses (total nurses = 425). The questionnaire only contained cases and questions in connection to HbA1c. No questions were included detailing the demographics of the responders, except for the specific role as caregiver. The responses to Question A (table 1A, figure 1A) show that a large number of the nurses (44%) and only a small number of the physicians (4%) were not aware of the inherent uncertainty of the HbA1c result. When comparing the responses of the two groups of nurses, they were not significantly different from each other (p = 0.714, Bonferroni corrected). The responses to Case B (table 1B, figure 1B) show that a cut-off point of 7.0% (53 mmol/mol) is regarded as a signal for treatment changes by 19.8% of the healthcare professionals.
professionals, and a level of 7.5% (58 mmol/mol) is regarded by 32.2% of the healthcare professionals as a sufficiently powerful signal to consider starting insulin. Overall there was a significant difference in the responses between the three groups (p < 0.001); however, the difference between the diabetes specialised nurses and physicians was not significant (p = 0.051, Bonferroni corrected). Case C (table 1C, figure 1C) shows that a sustained HbA1c level between 7.0% (53 mmol/mol) and 7.5% will prompt the vast majority (87%) of the healthcare providers to consider changing therapy in order to reach the predefined target value. Of them, 29.9% chose a level of 7.5%, in accordance with a difference of 0.6% (6 mmol/mol). Almost all other respondents (57%) chose a value between 7% and 7.4%. Overall the responses differed significantly between the groups (p < 0.001). PCPN were mainly responsible for this difference since they were more inclined to choose a level below 7.2%. Physicians
and DSN did not differ significantly from each other (p = 0.084, Bonferroni corrected). Case D (table 1D, figure 1D) provides a somewhat mixed response, with healthcare professionals tending to either start treatment changes with an HbA1c which stays at a consistently higher level of 7.3% (56 mmol/mol) or, again, at the cut-off point of 7.5% (58 mmol/mol) and 7.0% (53 mmol/mol). PCPN seem more focused on trying to reach lower HbA1c values than doctors (p < 0.001), specifically to reach the treatment goal of 7.0% (53 mmol/mol), whereas the responses of physicians and diabetes specialised nurses were not significantly different (p = 0.201, Bonferroni corrected). Case E addresses which change in HbA1c is considered sufficient to allow the conclusion that glucose regulation has improved after treatment adjustment. A change of 1.0% (11 mmol/mol) was considered to be clinically relevant by 32.6% of the healthcare professionals, whereas 29.8% thought 0.5% (5.5 mmol/mol) was clinically relevant. There was no significant difference (p = 0.28) in responses between the different healthcare professionals (P, DSN and PCPN). Case F (table 1F, figure 1F) shows that especially DSN (40.0%) and PCPN (54.8%) seem to conclude that glucose regulation has worsened even when the HbA1c value was the same or only slightly (0.1% (1 mmol/mol)) increased. The difference in responses between these two groups was not significant (p = 0.186, Bonferroni corrected). A major portion of the doctors (57.1%) follow the clinically relevant change of 0.5% (5.5 mmol/mol) or 1.0% (11 mmol/mol) at an HbA1c value to confirm our findings. Furthermore, a limitation of the present study is the low response to the internet survey. Since healthcare systems may be organised different in different countries, the results presented here may preclude generalisation. An international survey among different healthcare providers should be performed to confirm our findings. Furthermore, a limitation of the present study is the low response to the internet survey.

In general, guidelines consider a difference of 0.5% (5.5 mmol/mol) to be clinically significant. However, a recent study showed that the analytical performance of some HbA1c assays may not be accurate enough to sufficiently support treatment decisions in the management of patients with diabetes when differences in serial HbA1c measurements amount to 0.5% (5.5 mmol/mol) or less. Combining this with the outcome of this survey, we can conclude that many of the nurses may react to HbA1c outcome variations based on the variability of the HbA1c method used instead of the true changes in the degree of glucose control. As a consequence, this could lead to undue treatment changes with accompanying costs and/or inconvenience for the patient.

**DISCUSSION**

The results of this study indicate that nurses seem to be well aware of the importance of HbA1c for the management of diabetes, but are now overly reacting to too small changes in the value of HbA1c observed in their patients. This observation could partly be explained by the fact that most of the nurses consider an HbA1c value to be an absolute value and are less aware of the fact that every HbA1c result has uncertainty based on the analytical performance of the HbA1c method used. As a consequence, nurses tend to consider treatment changes based on very small or even no differences in subsequent HbA1c results. Indeed, physicians and nurses interpret HbA1c differently in concluding that there is a decline or improvement of glycaemic control. A decrease of at least 0.5% (5.5 mmol/mol) or 1.0% (11 mmol/mol) at an HbA1c value of 9.0% (75 mmol/mol) after adjustment of therapy is considered sufficient by all healthcare professionals to allow the conclusion that glucose regulation has improved.

In contrast, a very small or no increase of HbA1c is considered by most of the nurses as sufficient to come to the conclusion that glucose regulation has worsened.

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This limited response may have led to a non-response bias. Unfortunately, data on the characteristics of the non-respondents could not be compared with the characteristics of responders, since demographic data were lacking for both groups, thus preventing proper assessment of the magnitude of this potential bias.

In conclusion, significant differences in interpretation of (changes in) HbA1c results between physicians and nurses exist. Nurses consider therapy changes based on very small changes in HbA1c, whereas physicians preferably agree to the clinically relevant change of 0.5% (5.5 mmol/mol). Changing therapy based on relatively small changes in HbA1c might lead to undue adjustments in the treatment of patients with diabetes. There is a clear need for more training for all diabetes care professionals about both the clinical significance and accuracy of HbA1c results. The authors are planning a follow-up study to further explore the observed differences between the diabetes healthcare professionals with respect to interpretation of HbA1c.

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DISCLOSURES

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