

Diabetes in Urban African-Americans. XVII. Availability of Rapid HbA_{1c} Measurements Enhances Clinical Decision-Making

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OBJECTIVE — To assess the impact of rapid-turnaround HbA_{1c} results on providers' clinical decision-making and on follow-up HbA_{1c} levels.

RESEARCH DESIGN AND METHODS — The research design was a randomized clinical trial in which rapid HbA_{1c} results were made available to providers on even days of the month (rapid, *n* = 575), but delayed by 24 h on odd days (conventional, *n* = 563). Adjustment of therapy for patients with type 2 diabetes was considered appropriate if therapy was intensified for HbA_{1c} values >7% or not intensified for HbA_{1c} values ≤7%. A post-hoc analysis was also performed using patients (*n* = 574) who returned for follow-up 2–7 months later to ascertain the effect of rapid HbA_{1c} availability on subsequent glycemic control.

RESULTS — Rapid HbA_{1c} availability resulted in more appropriate management compared with conventional HbA_{1c} availability (79 vs. 71%, *P* = 0.003). This difference was due mainly to less frequent intensification when HbA_{1c} levels were ≤7% (10 vs. 22%, *P* < 0.0001) and slightly to more frequent intensification for patients with HbA_{1c} values >7% (67 vs. 63%, *P* = 0.33). For both groups, intensification was greatest for patients on insulin (51%) compared with patients on oral agents (35%) and diet alone (14%) (*P* < 0.0001). Regression analysis confirmed that providers receiving conventional HbA_{1c} results were more likely to intensify therapy in patients who already had HbA_{1c} levels ≤7%. Over 2–7 months of follow-up, HbA_{1c} rose more in patients with conventional HbA_{1c} results compared with rapid results (0.8 vs. 0.4%, *P* = 0.02). In patients with initial HbA_{1c} >7%, rapid HbA_{1c} results had a favorable impact on follow-up HbA_{1c} independent of the decision to intensify therapy (*P* = 0.03).

CONCLUSIONS — Availability of rapid HbA_{1c} determinations appears to facilitate diabetes management. The more favorable follow-up HbA_{1c} profile in the rapid HbA_{1c} group occurs independently of the decision to intensify therapy, suggesting the involvement of other factors such as enhanced provider and/or patient motivation.

Diabetes Care 22:1415–1421, 1999

Populations enriched with African-American patients are at increased risk of both diabetes (1–3) and diabetes complications (4–6), and emerging evidence suggests that the high prevalence of microvascular complications may be attrib-

utable to poor metabolic control. Although ethnic minority patients and Caucasians have similar rates of diabetes complications when HbA_{1c} values are comparable (4–6), African-Americans have been shown to have higher HbA_{1c} levels than Caucasians in many large clinics (7–10). Thus, therapy directed at reducing HbA_{1c} levels in minority patients with diabetes should lead to a decreased incidence of microvascular complications (11,12) and also help to lessen the enormous financial burden attributable to diabetes (13).

Intensive diabetes management is currently being promoted as a way to improve glycemic control. Intensification of diabetes therapy during patient visits can be guided by records of home blood glucose monitoring, prior HbA_{1c} levels, and/or glucose measurements during the visit. Unfortunately, reliability and availability of home blood glucose monitoring records are highly variable. Hoskins et al. (14) have suggested that up to three-fourths of patients may record blood glucose levels that are lower than actual values, and Cowie and Harris (15) have found that only 30% or less of patients on insulin monitor their glucose at least once daily. Moreover, we have found that health care providers tend to disregard previous HbA_{1c} levels and guide management decisions largely on the basis of glucose levels determined during patient visits (16). While a single plasma glucose measurement is useful in reflecting chronic glycemic status (17), HbA_{1c} remains the standard indicator of glycemic control (18). Fortunately, available instrumentation now permits rapid and valid on-site measurement of HbA_{1c} (19).

Previous investigations in our Diabetes Clinic had focused on stepped diabetes care, clinical decision-making, and monitoring of providers' performance concerning intensive diabetes management (16,17,20). Because there is limited understanding of the influence of HbA_{1c} levels on clinical decision-making, we used a prospective randomized controlled study design to compare rapid availability of HbA_{1c} levels (during office visits) with that of conventional avail-

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Received for publication 8 March 1999 and accepted in revised form 4 June 1999.

Abbreviations: ADA, American Diabetes Association; ANOVA, analysis of variance.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

ability (the next day). In an outpatient specialty diabetes clinic, we assessed the impact of such determinations on both clinical decision-making (whether or not to intensify therapy) and subsequent diabetes control (HbA_{1c} levels 2–7 months later).

RESEARCH DESIGN AND METHODS

Setting

The study was conducted at the Diabetes Clinic of the Grady HealthCare System. This outpatient facility provides care for ~950 new and 5,000 returning patients each year. Assignment as type 2 diabetes is based on clinical criteria, which include age of onset, absence of ketosis, history of management without insulin, presence of obesity, and presence of apparent type 2 diabetes in at least one first-degree relative. The population served is urban and economically disadvantaged; <10% of patients have commercial health insurance and ~50% have no third-party coverage at all (20). The functional health literacy of most patients in this community is inadequate to marginal (21). At each visit, patients are seen initially by a nurse provider who continues or modifies management and seen subsequently by a physician with subspecialty training in endocrinology who reviews and/or amends the plan for care.

Our goal of diabetes management is to achieve HbA_{1c} levels ≤7.0%. Because rapid-turnaround HbA_{1c} values have not previously been available during patient visits, the Diabetes Clinic protocol calls for advancement of therapy if fasting plasma glucose is ≥7.8 mmol/l (140 mg/dl) or random plasma glucose ≥10.0 mmol/l (180 mg/dl). If an emphasis on dietary therapy does not result in adequate metabolic control during the first 2 months after presentation to the unit, then pharmacological therapy is to be added or intensified at the 2-, 4-, and 6-month return visits, irrespective of whether or not patients bring home blood glucose records or have missed intervening appointments.

Study design

Between 21 July 1997 and 30 November 1997, all patients had HbA_{1c} levels determined during their visits. Only patients with type 2 diabetes were included in the analysis. The research design was a randomized clinical trial in which patients were randomized to have HbA_{1c} values immediately available to their providers

Table 1—Patient characteristics

	Conventional HbA _{1c} group		Rapid HbA _{1c} group	
	Entire	With follow-up HbA _{1c}	Entire	With follow-up HbA _{1c}
n	563	296	575	278
Age (years)	58 ± 0.5	59 ± 0.7	58 ± 0.5	60 ± 0.7
% Female	67	68	69	69
% Black	92	90	91	92
BMI (kg/m ²)	32.7 ± 0.3	33.2 ± 0.4	32.7 ± 0.3	32.5 ± 0.4
Duration (years)	8.1 ± 0.3	7.2 ± 0.4	7.9 ± 0.3	7.3 ± 0.4
% Diet/oral/insulin	17/38/45	17/42/42	17/37/46	19/33/48
Years enrolled in diabetes clinic	2.7 ± 0.1	2.7 ± 0.1	2.9 ± 0.1	2.8 ± 0.1
Initial HbA _{1c} (%)	7.5 ± 0.1	7.2 ± 0.1	7.8 ± 0.1	7.5 ± 0.1

Continuous variables are results ± SEM.

(rapid) or made available to the provider after the patient had left the clinic (conventional). For simplicity, rapid HbA_{1c} results were made available to diabetes care providers on even days of each month. On odd days, HbA_{1c} was measured, but access to results was delayed to mimic conventional availability. A fasting or random plasma glucose was determined on all patients and the results communicated to the providers during patient visits. Because dietary therapy rather than intensification of pharmacological treatment was stressed for each patient with type 2 diabetes during the first 2 months of follow-up, only visits at least 2 months after initial presentation were included in the study. If a patient was seen in the clinic more than once during this time period, only the last visit was included in the analysis.

A post hoc analysis, which was not part of the original randomized design, was also completed using patients who had HbA_{1c} data available between 2–7 months after the initial study visit. The timing of follow-up visits, compliance with appointments, and success of phlebotomy for the remainder of the patients were not known. Follow-up visits were only incorporated into the study if no intervening visit occurred between the initial visit and the follow-up visit.

For each visit, patients' demographics, plasma glucose, HbA_{1c}, and type and dosage of all diabetes-related medications were entered into a computerized database. We defined intensification of therapy as the addition of a new agent (oral agent or insulin) or an increase in dose of an existing medication. In accordance with our consensus management guidelines (16), which reflect the goals of glycemic control advanced by the American Diabetes Association (ADA) (18), any patient with a current

HbA_{1c} level >7.0% was considered eligible for intensification of therapy. Accordingly, percent intensification was expressed as 100 × (number of patients intensified)/(number of patients eligible for intensification). For the purposes of this study, diabetes management was considered appropriate 1) for patients with HbA_{1c} values >7% who had their therapy intensified and 2) for patients with HbA_{1c} values ≤7% who did not have their therapy intensified (recognizing that therapeutic goals for some individual patients may result in intensification of therapy based on available glucose levels even though HbA_{1c} levels are within the goal range). HbA_{1c} was determined using a Boehringer Mannheim turbidimetric immunoinhibition assay, with an interassay coefficient of variation of ≤3.83%. The study was approved by the Human Investigations Committee at Emory University.

Statistical analysis

We used χ² tests and two-tailed unpaired *t* tests to evaluate differences in baseline characteristics. χ² tests were also used to compare frequency of treatment intensification between groups. A *P* value <0.05 was considered significant and a Bonferonni correction was used where applicable. Multiple logistic regression analysis was used to compare the influence of age, race, sex, BMI, type of diabetes, duration of diabetes, HbA_{1c}, fasting plasma glucose, and availability of HbA_{1c} level on the rate of intensification. In patients who had follow-up HbA_{1c} data available, paired *t* tests and repeated-measures analysis of variance (ANOVA) were used to evaluate for improvement in HbA_{1c} over time between groups; unpaired *t* tests and Mann-Whitney tests were used to evaluate for differences in quantity of dose adjustment between

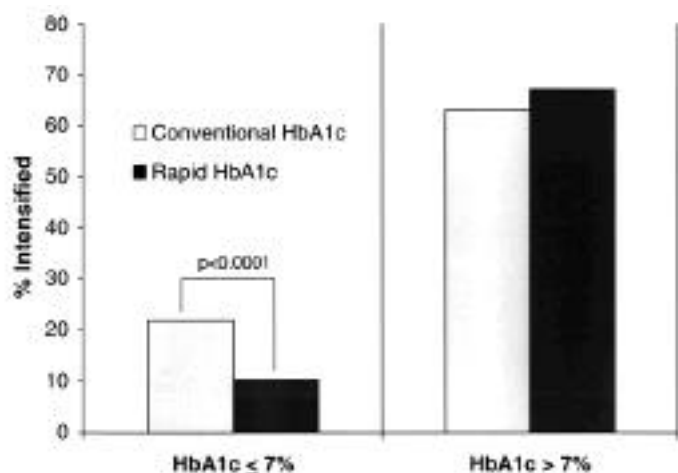


Figure 1—Therapy intensification according to HbA_{1c} level and availability of HbA_{1c}. Total visits analyzed equals 1,138 (HbA_{1c} ≤ 7%, n = 615; HbA_{1c} > 7%, n = 523).

groups. StatView version 5.0 (SAS Institute, Cary, NC) was the statistical software used for the analyses.

RESULTS

Subjects

A total of 1,138 patients were included in the study; their characteristics are outlined in Table 1. The majority of subjects were African-American and of middle age; all patients had type 2 diabetes. On even days of the months, 575 patients were seen with rapid HbA_{1c} availability. On odd days, 563 patients were seen with conventional HbA_{1c} availability. Randomization appeared adequate, with no significant differences between groups with respect to age, duration of diabetes, BMI, age at diagnosis, sex, and race. There were 574 patients (296 from the conventional HbA_{1c} group and 278 from the rapid HbA_{1c} group) who had follow-up HbA_{1c} levels documented 2–7 months after their initial study visit.

Therapy intensification for conventional and rapid HbA_{1c} groups

Overall, management was significantly more appropriate in the rapid HbA_{1c} group than in the conventional HbA_{1c} group (79 vs. 71%, $P = 0.003$). To determine the subgroup of patients responsible for this difference, patients were stratified into two groups: well controlled with HbA_{1c} values ≤ 7% and not well controlled with HbA_{1c} values > 7%. When HbA_{1c} was ≤ 7%, providers intensified twice as often with conventional delayed access to HbA_{1c} results compared with rapid results (22 vs. 10%, respectively, $P < 0.0001$) (Fig. 1). This is largely attrib-

uted to the subgroup of patients with HbA_{1c} ≤ 7% and fasting plasma glucose ≥ 7.8 mmol/l (140 mg/dl), for whom providers intensified therapy 46% of the time with conventional HbA_{1c} availability compared with 26% of the time when HbA_{1c} results were available immediately ($P = 0.03$). For patients with HbA_{1c} levels > 7%, the overall rates of intensification were 63 and 67%, respectively, on days with conventional and rapid HbA_{1c} results ($P = 0.33$) (Fig. 1). When therapy was intensified, the magnitude of dosage increase did not differ between conventional and rapid HbA_{1c} groups (data not shown).

Treatment modality

Insulin-treated patients had their therapy intensified more often than patients on oral

agents (51 vs. 35%, $P < 0.0001$), who had therapy intensified more frequently than patients on diet alone (35 vs. 14%, $P < 0.0001$). These differences remained significant on both rapid and conventional HbA_{1c} days and for HbA_{1c} values either ≤ 7.0% or > 7.0% (Fig. 2).

Regression analysis

Multiple logistic regression was used to determine factors contributing to the decision to intensify therapy. Sex, race, age, duration of diabetes, and BMI did not contribute significantly in any model and subsequently were not included in the final equations. For the group as a whole, multiple logistic regression confirmed that providers were more likely to intensify therapy for patients with higher fasting glucose and HbA_{1c} levels and for patients treated with insulin or oral agents, irrespective of availability of HbA_{1c} results at the time of the visit (Table 2).

Regression analysis was also performed within the subsets of patients with HbA_{1c} values ≤ 7% and > 7% (Table 2). In patients with HbA_{1c} levels ≤ 7%, providers were more likely to intensify pharmacological therapy when glucose levels were high and less likely to intensify therapy on days with rapid HbA_{1c} results (i.e., when they were made aware that the HbA_{1c} level was ≤ 7%). However, when the regression analysis was restricted to patients with HbA_{1c} values > 7%, only fasting plasma glucose influenced the decision to intensify therapy; providers responded to elevated fasting plasma glucose (present in 80% of these cases), without a significant further

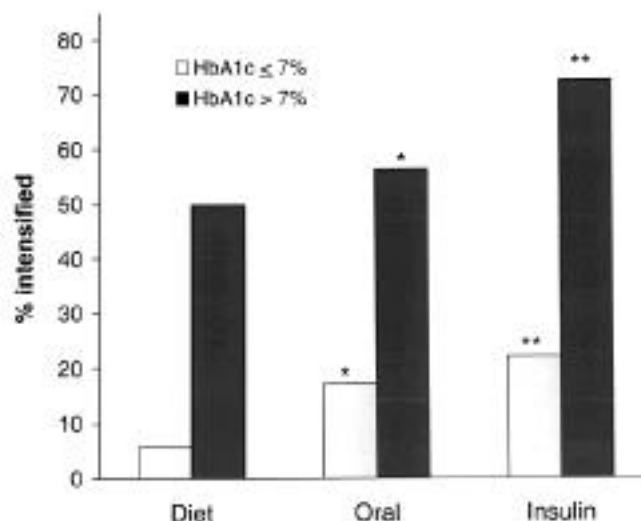


Figure 2—Intensification of diabetes therapy according to treatment regimen and HbA_{1c} level. Total visits analyzed equals 1,138 (diet, n = 192; oral agents, n = 428; insulin, n = 518). * $P < 0.0001$ for oral vs. diet; ** $P < 0.0001$ for insulin vs. diet and oral.

Table 2—Multiple logistic regression analysis showing independent contributions of HbA_{1c} availability, therapy, HbA_{1c} result, and fasting plasma glucose to the decision to intensify therapy

	Contribution to intensification		
	Whole group	Subgroup with HbA _{1c} ≤7%	Subgroup with HbA _{1c} >7%
Rapid HbA _{1c} availability	NS	—	NS
Oral agent treatment	+	+	NS
Insulin treatment	+	+	NS
HbA _{1c}	+	NS	NS
Fasting plasma glucose	+	+	+

+, Significant direct correlation with decision to intensify ($P < 0.05$). —, Significant indirect correlation with decision to intensify ($P < 0.05$). NS, no significant correlation with decision to intensify.

contribution from rapid availability of HbA_{1c} results.

Follow-up HbA_{1c} levels

A total of 574 patients had a follow-up HbA_{1c} level available 2–7 months subsequent to their study visit (mean 3.8 months). Baseline characteristics for this subset are shown in Table 1. The proportion of patients from each group with follow-up data available and their demographic characteristics were similar between conventional and rapid HbA_{1c} groups. Patients in the conventional HbA_{1c} group had a mean initial HbA_{1c} of 7.2% and a substantially higher follow-up HbA_{1c} of 8.0% ($P < 0.0001$); patients in the rapid HbA_{1c} group had a mean initial HbA_{1c} of 7.5% and a smaller increase in follow-up HbA_{1c} to 7.9% ($P = 0.0005$). Repeated-measures ANOVA demonstrated that these detriments in HbA_{1c} were significantly larger in the group with conventional HbA_{1c} results ($P = 0.02$).

To focus on patients with poor glycemic control at the initial visit, we separately analyzed patients with initial HbA_{1c} levels ≤7% and >7% (Table 3). In patients already well controlled with initial HbA_{1c} levels ≤7%, 175 subjects were in the conventional HbA_{1c} group and showed a mild increase in HbA_{1c} from 6.0 to 6.9% ($P < 0.0001$); 157 subjects were in the rapid HbA_{1c} group and showed a similar but smaller increase from 6.1 to 6.7% ($P < 0.0001$) (Fig. 3A). Within the subgroup of patients with initial HbA_{1c} values >7%, 121 patients in the conventional HbA_{1c} group had a mean initial HbA_{1c} level of 8.9% that increased significantly on follow-up to 9.6% ($P = 0.006$); 121 patients in the rapid HbA_{1c} group had a mean initial HbA_{1c} level of 9.2% that remained unchanged on follow-up with a mean of 9.3% ($P = 0.69$) (Fig. 3B).

We then attempted to determine if more frequent intensification of pharmacological therapy was responsible for the more favorable follow-up HbA_{1c} pattern seen with rapid HbA_{1c} results in patients with initial HbA_{1c} >7%. In patients who had their therapy intensified, HbA_{1c} increased nonsignificantly in the conventional HbA_{1c} group (9.4–9.9%, $P = 0.16$), with even less change in the rapid HbA_{1c} group (9.6–9.9%, $P = 0.33$) (Fig. 4A); the magnitude of dosage increase did not differ between conventional and rapid HbA_{1c} groups (data not shown). However, in patients whose pharmacological therapy was not intensified, HbA_{1c} levels worsened significantly in the conventional HbA_{1c} group (8.3–9.3%, $P = 0.03$), but trended toward improvement in the rapid HbA_{1c} group (8.4–8.2%, $P = 0.45$) (Fig. 4B). Repeated-measures ANOVA showed that for patients with initial HbA_{1c} levels >7%, rapid availability of HbA_{1c} results contributed significantly to improvement in HbA_{1c} ($P = 0.03$), independently of intensification of therapy.

Table 3—Patient characteristics for subgroup with follow-up HbA_{1c} data available

	Conventional HbA _{1c} group		Rapid HbA _{1c} group	
	Initial HbA _{1c} ≤7%	Initial HbA _{1c} >7%	Initial HbA _{1c} ≤7%	Initial HbA _{1c} >7%
n	175	121	157	121
Age (years)	61 ± 0.9	57 ± 1.1*	61 ± 0.9	58 ± 1.1*
Initial BMI (kg/m ²)	33.1 ± 0.6	33.3 ± 0.6	32.1 ± 0.6	33.0 ± 0.6
Change in BMI (kg/m ²)	0.20 ± 0.10	−0.19 ± 0.17	0.28 ± 0.13	0.03 ± 0.10
Duration (years)	6.4 ± 0.6	8.3 ± 0.7*	6.3 ± 0.5	8.6 ± 0.6*
% Diet/oral/insulin	23/43/33	7†/40/54†	27/34/38	8†/31/60*
Months' follow-up	3.8 ± 0.1	3.8 ± 0.1	3.8 ± 0.1	3.8 ± 0.1
Initial HbA _{1c} (%)	6.0 ± 0.0	8.9 ± 0.2†	6.1 ± 0.0	9.2 ± 0.2†
Follow-up HbA _{1c} (%)	6.9 ± 0.1‡	9.6 ± 0.3†§	6.7 ± 0.1‡	9.3 ± 0.2†

Data are means ± SEM. * $P < 0.05$ compared with HbA_{1c} ≤7% group; † $P < 0.0001$ compared with HbA_{1c} ≤7% group; ‡ $P < 0.0001$ compared with initial HbA_{1c}; § $P = 0.006$ compared with initial HbA_{1c}.

CONCLUSIONS— HbA_{1c} remains the standard measure of glycemic control used to evaluate diabetes management and predict long-term outcomes (11,12). Rapid HbA_{1c} analyzers can now provide quick and reliable HbA_{1c} results, with a cost comparable to that of the traditional high-performance liquid chromatography method (22). The ADA currently recommends achieving an HbA_{1c} level ≤7% based on studies that have shown prevention or delay in progression of diabetes microvascular complications when lower HbA_{1c} levels are achieved (18). Furthermore, current evidence indicates a relative urgency to improve HbA_{1c} levels in patients with diabetes. Data from the Kumamoto Study suggests that the divergence in the incidence of microvascular complications between intensively and conventionally treated patients with type 2 diabetes was apparent as early as 6 months after intensive therapy was begun (12).

Numerous factors may interfere with the process of intensification of therapy and achievement of target HbA_{1c} levels. We and others have observed that patients frequently do not perform home blood glucose monitoring as requested (15) and often forget to bring their records to the clinic. We have also identified suboptimal provider adherence to management guidelines as a barrier to intensification of diabetes therapy (16). Perceptions by the provider that glycemic control is improving or that patients are noncompliant with diet or medications appear to be the most common reasons for failure to intensify therapy in poorly controlled patients (23). These obstacles to intensification could result in extended periods of poor glycemic control and the development or worsening of diabetes complications.

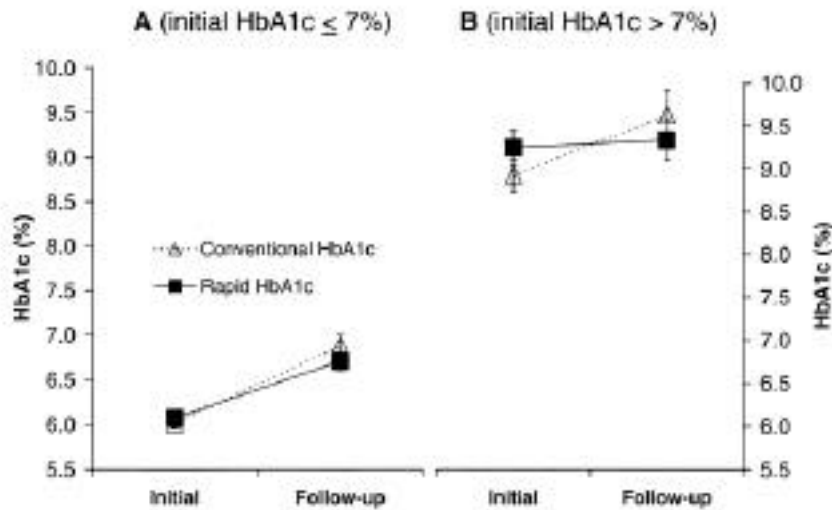


Figure 3—Initial and follow-up HbA_{1c} values in conventional and rapid HbA_{1c} groups. A: Initial HbA_{1c} ≤ 7%. B: Initial HbA_{1c} > 7%. Total visits analyzed equals 574 (conventional and initial HbA_{1c} ≤ 7%, n = 175; rapid and initial HbA_{1c} ≤ 7%, n = 157; conventional and initial HbA_{1c} > 7%, n = 121; rapid and initial HbA_{1c} > 7%, n = 121). Repeated-measures ANOVA for conventional versus rapid HbA_{1c}: P = 0.13 for initial HbA_{1c} ≤ 7%, P = 0.07 for initial HbA_{1c} > 7%, P = 0.02 for combined group.

In this study, our objective was to determine the impact of rapid HbA_{1c} results on providers' adherence to management guidelines. Larsen et al. (24) demonstrated in 1990 that physician awareness of HbA_{1c} levels, in addition to home glucose records, can result in improved HbA_{1c} levels. Another report suggested that physicians value the availability of a current HbA_{1c} level and claim that they would rely on it predominantly in intensifying therapy (25). However, the impact of a rapid-turn-around HbA_{1c} level on either clinical decision-making or subsequent glycemic control has not previously been studied in a controlled prospective manner.

Our results show that having an HbA_{1c} result available at the time of the visit improves clinical decision-making. Specifically, it facilitates the identification of patients who are already appropriately controlled (with HbA_{1c} levels ≤ 7%) and helps to avoid further intensification of therapy in such patients. Although serious hypoglycemia in patients with type 2 diabetes is rare (26–28), avoiding further intensification when the HbA_{1c} is within goal range should reduce the risk of hypoglycemia. Moreover, there is some evidence that achieving HbA_{1c} values < 7.0% may further reduce microvascular complications (29,30). The availability of rapid HbA_{1c} results would be even more likely to reduce the frequency of hypoglycemia if lower goals for HbA_{1c} were to be established. Our results also show that rapid

HbA_{1c} availability tends to increase intensification of therapy in patients who are poorly controlled, although this effect was not statistically significant in our unit where intensification is already high (31).

Available follow-up data enabled analysis of the impact of rapid HbA_{1c} results on subsequent glycemic control. Because the initial study design did not project assess-

ment of follow-up HbA_{1c} levels at a specific interval, it is possible that our post-hoc examination may have selected a biased sample. However, the two groups had similar clinical characteristics, and average follow-up intervals were comparable as well. There was a significant but small increase in HbA_{1c} in the group with rapid HbA_{1c} results, while the group with conventional HbA_{1c} availability showed a significantly larger increase of HbA_{1c} over time (0.4 vs. 0.8%, P = 0.02). When initial HbA_{1c} levels were ≤ 7%, patients in both groups remained adequately controlled during the follow-up period. In patients with an initial HbA_{1c} level > 7%, there was no change in HbA_{1c} over time in the rapid HbA_{1c} group, while HbA_{1c} deteriorated significantly when HbA_{1c} results were delayed. A deterioration in HbA_{1c} over time was also found in the U.K. Prospective Diabetes Study, although over a much longer period of follow-up (32). Presumably, this trend could be reversed by more aggressive use of pharmacological therapy. With the recognition that some patients may respond poorly to conventional stepped care protocols and need more intensive management, we are now in the process of revising our therapeutic paradigms.

We suspect that the availability of rapid HbA_{1c} results may have benefits beyond facilitating adjustment of pharmacological therapy by providers. Among patients with

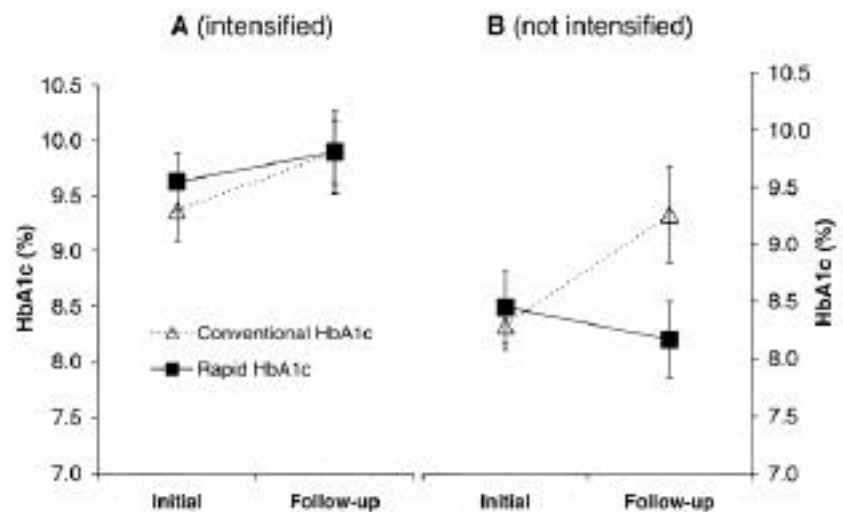


Figure 4—Effect of HbA_{1c} availability and intensification of therapy on HbA_{1c} when initial HbA_{1c} is > 7%. A: Diabetes therapy intensified. B: Diabetes therapy not intensified. Total visits analyzed equals 242 (conventional and intensified, n = 71; rapid and intensified, n = 82; conventional and not intensified, n = 50; rapid and not intensified, n = 39). Repeated-measures ANOVA: P = 0.03 conventional vs. rapid, P = 0.88 intensification vs. no intensification.

initial HbA_{1c} values >7% who did not have their therapy intensified, those in the conventional HbA_{1c} group showed a significant deterioration in HbA_{1c}, while those in the rapid HbA_{1c} group had a small nonsignificant improvement (Fig. 4). A similar trend was seen in those who had therapy intensified. One conceivable explanation is that greater provider confidence in the true state of glycemic control led to more persuasive discussions during patient encounters, encouraging patients toward greater compliance with diet, exercise, and medications in the rapid HbA_{1c} group. However, neither group had a significant change in BMI, and no measures of compliance or physical activity were available for the current analysis. Therefore, further studies will be required to test such a hypothesis.

Rapid HbA_{1c} availability may have an even greater impact on clinical decision-making in the primary care setting. Our Diabetes Clinic practices aggressive intensification of therapy, achieving in 1996 an average HbA_{1c} level of 7.2% in patients who maintained their scheduled follow-up visits (31); further improvement in intensification practices may be difficult to observe in our setting. In a non-specialty clinic where diabetes therapy may be less structured (33), an enhancement of intensification of diabetes therapy may be more pronounced as a result of rapid availability of HbA_{1c}. To test this hypothesis, a trial of rapid HbA_{1c} measurement in a primary care environment will be needed.

Acknowledgments— This work was supported in part by awards from the Agency for Health Care Policy and Research (HS-09722; to D.C.Z., D.L.G., L.S.P., and I.M.E.-K.) and the National Institutes of Health (DK-33475, DK-48124; to L.S.P.).

We would like to thank the nurse providers and laboratory staff of the Diabetes Clinic for their contribution to this project.

References

- Harris MI: Epidemiological correlates of NIDDM in Hispanics, whites and blacks in the U.S. population. *Diabetes Care* 14: 639–648, 1991
- Harris MI: Non-insulin-dependent diabetes in black and white Americans. *Diabetes Metab Rev* 6:71–90, 1990
- Bonham GS, Brock DB: The relationship of diabetes with race, sex, and obesity. *Am J Clin Nutr* 41:776–783, 1985
- Wetterhall SF, Olson DR, DeStefano F, Stevenson JM, Ford ES, German R, Will JC, Newman JM, Sepe SJ, Vinicor F: Trends in diabetes and diabetic complications, 1980–1987. *Diabetes Care* 15:960–967, 1992
- Rabb MF, Gagliano DA, Sweeney HE: Diabetic retinopathy in blacks. *Diabetes Care* 24:1202–1206, 1990
- National Center for Health Statistics and Hospital Care Statistics Branch (Eds.): *Summary: National Hospital Discharge Survey*. Hyattsville, MD, Public Health Service, 1988
- Delamater AM, Albrecht DR, Postellon DC, Gutai JP: Racial differences in metabolic control of children and adolescents with type I diabetes mellitus. *Diabetes Care* 14:20–25, 1991
- Weatherspoon LJ, Kumanyika SK, Ludlow R, Schatz D: Glycemic control in a sample of black and white clinic patients with NIDDM. *Diabetes Care* 17:1148–1153, 1994
- Summerson JH, Konen JC, Dignan MB: Race-related differences in metabolic control among adults with diabetes. *South Med J* 85:953–956, 1992
- Eberhardt MS, Lackland DT, Wheeler FC, German RR, Teutsch SM: Is race related to glycemic control? An assessment of glycosylated hemoglobin in two South Carolina communities. *J Clin Epidemiol* 47:1181–1189, 1994
- The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 329:977–986, 1993
- Ohkubo Y, Kishikawa H, Araki E, Miyata T, Isami S, Motoyoshi S, Kojima Y, Furuyoshi N, Shichiri M: Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract* 28:103–117, 1995
- American Diabetes Association: Economic consequences of diabetes mellitus in the U.S. in 1997. *Diabetes Care* 21:296–309, 1998
- Hoskins PL, Alford JB, Handelsman DJ, Yue DK, Turtle JR: Comparison of different models of diabetes care on compliance with self-monitoring of blood glucose by memory glucometer. *Diabetes Care* 11:719–724, 1988
- Cowie CC, Harris MI: Ambulatory medical care for non-Hispanic whites, African-Americans, and Mexican-Americans with NIDDM in the U.S. *Diabetes Care* 20:142–147, 1997
- El-Kebbi IM, Ziemer DC, Musey VC, Gallina DL, Bernard AM, Phillips LS: Diabetes in urban African-Americans. IX. Provider adherence to management protocols. *Diabetes Care* 20:698–703, 1997
- El-Kebbi IM, Ziemer DC, Gallina DL, Phillips LS: Diabetes in African-Americans. VI. Utility of fasting or random glucose in identifying poor glycemic control. *Diabetes Care* 21:501–505, 1998
- American Diabetes Association: Standards of medical care for patients with diabetes mellitus. *Diabetes Care* 21:S23–S31, 1998
- Guerci B, Durain D, Leblanc H, Rouland JC, Passa P, Godeau T, Charbonnel B, Mathieu Daude JC, Boniface H, Monnier L, Dauchy F, Slama G, Drouin P: Multicenter evaluation of the DCA 2000 system for measuring glycated haemoglobin: DCA 2000 Study Group. *Diabetes Metab* 23: 195–201, 1997
- Ziemer DC, Goldschmid M, Musey VC, Domin WS, Thule PM, Gallina DL, Phillips LS: Diabetes in urban African-Americans. III. Management of type II diabetes in a municipal hospital setting. *Am J Med* 101:25–33, 1996
- Nurss JR, El-Kebbi IM, Gallina DL, Ziemer DC, Musey VC, Lewis S, Liao Q, Phillips LS: Diabetes in urban African Americans: functional health literacy of municipal hospital outpatients with diabetes. *Diabetes Educator* 23:563–568, 1997
- Cagliero E, Levina E, Nathan DM: Performance and cost analysis of HbA_{1c} assay with immediately available results (Abstract). *Diabetes* 45:298A, 1996
- El-Kebbi IM, Gallina DL, Dunbar VG, Phillips LS: Barriers to intensification of therapy in patients with NIDDM (Abstract). *Diabetes* 46:100A, 1997
- Larsen ML, Horder M, Mogensen EF: Effect of long-term monitoring of glycosylated hemoglobin levels in insulin-dependent diabetes mellitus. *N Engl J Med* 323:1021–1025, 1990
- Newman W: Immediate versus delayed availability of hemoglobin A_{1c}: impact on clinical decisions (Abstract). *Diabetes* 45:148A, 1996
- Abraira C, Colwell JA, Nuttall FQ, Sawin CT, Nagel NJ, Comstock JP, Emanuele MV, Levin SR, Hendersen W, Lee HS: Veterans Affairs Cooperative Study on glycemic control and complications in type II diabetes (VA CSDM): results of the feasibility trial. *Diabetes Care* 18:1113–1123, 1995
- Cusi K, Cunningham GR, Comstock JP: Safety and efficacy of normalizing fasting glucose with bedtime NPH insulin alone in NIDDM. *Diabetes Care* 18:843–851, 1995
- Colwell JA: The feasibility of intensive insulin management in non-insulin-dependent diabetes mellitus: implications of the Veterans Affairs Cooperative Study on glycemic control and complications in NIDDM. *Ann Intern Med* 124:131–135, 1996
- McCance DR, Hanson RL, Charles MA,

- Jacobsson LTH, Pettitt DJ, Bennett PH, Knowler WC: Comparison of tests for glycosylated haemoglobin and fasting and two hour plasma glucose concentrations as diagnostic methods for diabetes. *BMJ* 308:1323–1328, 1994
30. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 20:1183–1197, 1997
31. Phillips LS, El-Kebbi IM, Dunbar V, Ernst L, Gallina DL: Improved diabetes management over 5 years with nurse provider-led care at a large municipal hospital (Abstract). *Diabetes* 47:A2, 1998
32. UK Prospective Diabetes Study (UKPDS) Group: Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352:837–853, 1998
33. Ho M, Marger M, Beart J, Yip I, Shekelle P: Is the quality of diabetes care better in a diabetes clinic or in a general medicine clinic? *Diabetes Care* 20:472–475, 1997