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Prevalence of Undiagnosed and Suboptimally Controlled Diabetes by Point-of-care HbA1C in Unselected Emergency Department Patients

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Abstract

Objectives—The objective was to estimate the glycemic control of patients with known diabetes and to assess the prevalence of undiagnosed diabetes in an unselected emergency department (ED) population. Secondary objectives include evaluating the prevalence of undiagnosed diabetes in high-risk groups of ED patients such as Hispanic patients, African Americans, and patients with body mass index (BMI) ≥ 30 kg/m².

Methods—A convenience sample of adult ED patients was screened for diabetes using a National Glyco-hemoglobin Standardization Program–certified point-of-care (POC) glycated hemoglobin (HbA1C) meter at a single academic medical center during eight 24-hour periods. Diabetes was defined as HbA1C $\geq 6.5\%$, consistent with new American Diabetes Association (ADA) guidelines.

Results—Of the 1,611 patients evaluated in the ED during the study period, 313 were included in the study sample. Of these, 15% reported a history of diabetes, 42% of whom were suboptimally controlled. An additional 14% of the study sample was found to have previously undiagnosed diabetes. In our limited sample, the prevalence of previously undiagnosed diabetes in Hispanics, African Americans, and patients with BMI ≥ 30 kg/m² was 14, 27, and 22%, respectively.

Conclusions—Patients in our sample had a high prevalence of suboptimally controlled and undiagnosed diabetes. New POC HbA1C devices and simplified diagnostic criteria for diabetes significantly enhance the possibility of ED-based screening programs. Future research should validate our findings in a broader array of EDs and study the acceptance of such ED-based diabetes screening programs.

Previously, diabetes screening programs have been undermined by a complicated two-step diagnostic procedure that required multiple visits and a low prevalence of undiagnosed disease in community-dwelling patients (usually in the range of 1% to 3%).¹ Substantial changes in diagnostic criteria for diabetes (i.e., using a single glycated hemoglobin [HbA1C] percentage $\geq 6.5\%$ to define the condition), along with the development of reliable point-of-

care (POC) HbA1C meters, have increased the possibility of establishing successful screening programs outside primary care settings.^{2,3}

The emergency department (ED) serves as a point of entry for millions of medically needy Americans who may infrequently or ineffectively utilize routine health maintenance services.⁴ Importantly, ED-based public health screening programs focused on injury prevention, smoking cessation, and HIV detection have shown substantial promise.^{5–7} A first step toward developing an ED-based screening and intervention program for diabetes is understanding the prevalence of undiagnosed and poorly controlled diabetes in ED patients. The purpose of this pilot investigation was to: 1) determine the prevalence of undiagnosed diabetes in an unselected ED population, 2) detail the state of glycemic control among ED patients with known diabetes, and 3) estimate the prevalence of diabetes among high-risk groups (Hispanics, African Americans, and patients with body mass index [BMI] ≥ 30 kg/m²).

METHODS

Study Design

We conducted a prospective diabetes screening study of a convenience sample of ED patients at Massachusetts General Hospital, an urban, academic ED with approximately 80,000 annual ED visits. Institutional review board approval and written informed consent were obtained.

Study Setting and Population

English- or Spanish-speaking, noncritical adult (>18 years old) ED patients were eligible to participate. We excluded patients with high acuity or distress (based on the treating clinician's judgment of ability to participate in the study without interference in clinical care), altered mentation, acute psychiatric illness, or history of possible sexual assault.

Study Protocol

Research assistants were instructed to approach consecutive patients during four randomly selected weekday and four randomly selected weekend 24-hour periods from April 2007 to August 2007. After informed consent was obtained, enrolled patients were interviewed using a structured data form, and research assistants recorded demographic information, insurance status, medical history, and diabetes risk factors including BMI and family history of diabetes directly from the patient. There was no chart review. Subjects were also asked if they had a primary medical doctor (PMD) as a simple one-item question. Capillary HbA1C was measured with a National Glycohemoglobin Standardization Program–certified device (Bayer A1CNow+, Bayer Healthcare Diabetes Care, Sunnyvale, CA). Patients without known diabetes were considered to have “previously undiagnosed diabetes” if their ED POC HbA1C was $\geq 6.5\%$, consistent with new American Diabetes Association (ADA) guidelines.² Subjects with a known prior history of diabetes were considered to be suboptimally controlled if their HbA1C was $>7.0\%$ consistent with ADA categorization.² All subjects were informed of their screening results and given specific follow-up recommendations. No therapies were initiated as part of this study protocol.

Data Analysis

Statistical analyses were performed with Stata 10.1 (StataCorp, College Station, TX). Descriptive statistics with appropriate confidence intervals (CIs) were created. Median values and interquartile ranges (IQR) are given as the data were generally nonparametric. In this exploratory study, we did not conduct a formal sample size calculation, as we did not have any previously reported estimate of the proportion of patients with undiagnosed or

suboptimally controlled diabetes in the ED. We chose to conduct the study over eight 24-hour periods based on locally available resources.

RESULTS

During the study periods, 1611 patients were evaluated in the ED. Of 789 who met selection criteria, 355 were enrolled (282 refused, 152 were missed). Detailed quantifiable data regarding demographic characteristics, complaints, or disposition on subjects who were ineligible for study participation were not collected. Nonenrolled, eligible participants were older (mean 51 years vs. 42 years) than enrolled subjects. Other sociodemographic characteristics available for analysis (sex, race, and insurance status) were not statistically different between enrolled and nonenrolled patients (data not shown). Forty-two enrolled subjects were unable to complete the data collection due to illness or discharge prior to completion and were therefore excluded from analysis.

Ultimately, 313 remaining subjects were included in the analysis, and 48 (15%) had a self-reported history of diabetes. Among these 48 patients with known diabetes, the median HbA1C was 6.9% (IQR = 6.5%–8.5%), and 20 (42%) had HbA1C > 7.0%, indicating suboptimal control. Patients with known diabetes and suboptimal glycemic control had a median HbA1C of 8.1% (IQR = 7.5%–10.4%), and 18 of the 20 (90%) reported having a PMD. Within the remaining 265 subjects with no prior history of diabetes, 38 (14%) were found to have HbA1C ≥ 6.5% (median = 7.1, IQR = 6.6–7.5), thus meeting the new ADA definition of diabetes (Table 1). Thirty-five of the 38 patients (92%) with previously undiagnosed diabetes reported having a PMD. The prevalences of previously undiagnosed diabetes among Hispanics, African Americans, and patients with BMI ≥ 30 kg/m² were 14, 27, and 22%, respectively.

DISCUSSION

To the best of our knowledge, this is the first study to screen ED patients for diabetes using the new ADA HbA1C-based definition (≥ 6.5%).² In our sample of ED patients, over a quarter were affected by diabetes. On screening, 14% of our sample was found to have previously undiagnosed diabetes. An additional 15% of ED patients screened reported a history of diabetes, and 42% of these had suboptimal glycemic control. Of patients with either previously undiagnosed or suboptimally controlled diabetes, 90% reported having a primary care physician.

Typical opportunistic screening programs for diabetes in primary care or community settings have generally had yields between 1% and 3%.¹ Our finding that 14% of our sample had previously undiagnosed diabetes is the highest reported in the literature. We caution that these results must be considered preliminary due to the substantial proportion of nonenrolled patients (50%) that may have biased the results.

Public health screening and intervention programs can be feasible in the ED. Prior studies suggest that patients may accept these programs even when the target disease may be stigmatizing (as in HIV) or unrelated to the reason for visit (as in smoking or alcohol abuse).^{5–7} Barriers to widespread adoption of such screening programs include low incidence (HIV screening), ill-defined treatment approaches (alcohol abuse), and conditions that are often considered social, not medical (interpersonal or domestic violence).⁸ Undiagnosed diabetes, on the other hand, appears to be quite common in this ED population, has well-defined treatment approaches, and is clearly considered a medical problem. Further, diabetes has a long preclinical phase and early identification and treatment has been shown to result in cost-effective increases in quality-adjusted life-years.⁹ Still, patient

perceptions about the utility of such diabetes screening and their willingness to participate represent a large barrier to implementation. Indeed, in the present study, 35% of eligible patients refused to participate. Although we do not know the exact reason for these refusals, we must consider that potential subjects did not believe that diabetes screening was highly meaningful to them.

Previous work with diabetes screening has revealed that follow-up for confirmatory testing has been a major impediment to successful programs. Diagnostic strategies using fasting or 3-hour glucose tolerance tests have proven infeasible in the ED setting, as only 40% of patients with elevated glucose return for confirmatory testing under optimal conditions.¹⁰ Rapid, capillary POC HbA1C meters and a new definition of diabetes based on HbA1C measurement significantly enhance the possibility of ED-based diabetes screening. With an observed prevalence of 14%, and a price of \$6 to \$8 U.S. per test, the cost to uncover one patient with previously undiagnosed diabetes is \$50 to \$70.

The finding that over 90% of previously undiagnosed or suboptimally controlled patients with diabetes reported having a PMD further augments the call for screening in non-primary care settings. ED patients represent a high-risk group who may be infrequent users of the health care system and for whom screening programs may yield high dividends. The challenge of treating those who screen positive for diabetes, or those with poorly controlled diabetes, remains vexing. The emergency health care system, already faced with treating 119 million annual visits under increasingly crowded conditions, is ill-equipped to assume this role. Innovative approaches using nurses, case managers, and community health workers have been successfully employed in primary care settings and networks and may represent a viable option for ED populations with diabetes.¹¹ This study merely sought to evaluate the prevalence of undiagnosed and suboptimally controlled diabetes and did not seek to determine patient or physician acceptance of an ED-based screening strategy. Future research should focus on validating the findings and testing methods to successfully integrate patients with previously undiagnosed and poorly controlled diabetes into active management programs.

LIMITATIONS

We were only able to enroll 50% of eligible participants, primarily due to subject refusal to participate (35%) or simply being missed by the research assistants during the enrollment periods (15%). This may have introduced some selection bias into our study. Most demographic variables that were available were similar between enrolled and nonenrolled eligible patients. We did not, however, collect data on the triage acuity, chief complaint, disposition, or past medical history for non-enrolled patients. We observed that nonenrolled eligible patients were older than enrolled subjects, which might have a small effect of biasing our estimate downward. However, other, unmeasured variables in the nonenrolled patients, including potentially a self-perception among those who refused to participate that they had no realistic risk (perhaps they had been recently screened by their PMD) may have biased the results toward overestimating the prevalence of undiagnosed diabetes. Ultimately, the large proportion of refused and/or missed cases compels and leaves us uncertain as to the true prevalence of diabetes in this population and causes us to view these results as preliminary. Future research focused on minimizing nonenrolled patients would be critical to validating our findings. Another limitation of this study is that it was performed at a single academic medical center restricting the generalizability of findings. Additionally, this study site had a relatively small proportion of minority and low socioeconomic status patients compared with many EDs.

We cannot comment on the accuracy or the reasons for our finding that among study subjects with previously undiagnosed diabetes, 90% reported having a primary care physician. This finding simply points out that having a primary care physician does not protect the patient from undiagnosed diabetes. We did not attempt to determine whether each patient actually had a primary care physician, when they had their last visit, or whether the patient had been or should have been screened by for diabetes by the primary care physician.

CONCLUSIONS

Emergency department patients in our limited sample had a 14% prevalence of undiagnosed diabetes. Further, 42% of patients with known diabetes were suboptimally controlled. These findings, coupled with new point-of-care HbA1C testing devices and HbA1C-based definition of diabetes, may enhance the possibility of developing ED-based diabetes screening programs. Future research should confirm these findings in a broader array of EDs, study the feasibility of such programs, and test novel mechanisms to link patients with previously undiagnosed and poorly controlled diabetes to active management programs.

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Table 1

Characteristics of the Sample Divided Into Those With Known Prior History of Diabetes and Those Without Prior History of Diabetes

	Characteristics of Patients With Known Prior History of Diabetes		Characteristics of Patients Without Prior History of Diabetes	
	Patients With Known History of Diabetes but Suboptimal Glycemic Control (HbA1C > 7%)	Patients With Known History of Diabetes but Good Glycemic Control (HbA1C 7%)	Patients Screening Positive for Newly Diagnosed Diabetes (HbA1C 6.5%)	Patients Screening Negative for Diabetes (HbA1C < 6.5%)
Number	20 (42)	28 (58)	38 (14)	227 (86)
HbA1C, median (IQR)	8.1% (7.5–10.4)	5.8% (5.5–6.2)	7.0% (6.6–7.5)	5.8% (5.5–6.2)
Median age, yr	65	69	49	40
Female sex	11 (56)	12 (43)	17 (45)	107 (47)
Has a primary care physician	18 (90)	27 (96)	35 (92)	186 (82)
Race/ethnicity				
Not Hispanic, white	16 (80)	22 (79)	25 (66)	187 (83)
African American	0 (0)	3 (11)	6 (16)	16 (7)
Hispanic	2 (10)	3 (11)	2 (5)	12 (5)
Other	2 (10)	0 (0)	5 (13)	12 (5)
Education				
Less than high school	3 (15)	5 (18)	3 (8)	16 (7)
High school graduate	2 (10)	11 (39)	13 (34)	53 (23)
Some college	15 (75)	12 (43)	22 (58)	158 (70)
Income				
Less than \$40,000	9 (45)	13 (46)	14 (37)	58 (26)
More than \$40,000	4 (20)	4 (14)	14 (37)	92 (41)
Refused to answer	7 (35)	11 (55)	10 (26)	77 (34)
Insurance				
Any private	9 (45)	14 (50)	25 (66)	152 (67)
Medicaid ± Medicare	9 (45)	8 (29)	10 (26)	55 (24)
Medicare only	2 (10)	6 (21)	1 (3)	8 (4)
None	0 (0)	0 (0)	2 (5)	12 (5)
BMI				
BMI < 25	4 (20)	7 (25)	15 (39)	87 (38)
BMI 25–29.9	5 (25)	6 (21)	6 (16)	83 (37)
BMI ≥ 30	10 (50)	14 (50)	14 (37)	50 (22)
First-degree relative with diabetes	10 (50)	18 (64)	17 (45)	64 (28)
Hypertension	13 (65)	23 (82)	14 (37)	66 (29)
Dyslipidemia	11 (55)	16 (57)	11 (29)	61 (27)

Values are *n* (%) unless otherwise specified.

BMI = body mass index.