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Low Socioeconomic Status is Associated with Increased Risk for Hypoglycemia in Diabetes Patients: the Diabetes Study of Northern California (DISTANCE)

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Abstract

Background—Social risk factors for hypoglycemia are not well understood.

Methods—Cross-sectional analysis from the DISTANCE study, a multi-language, ethnically-stratified random sample of adults in the Kaiser Permanente Northern California diabetes registry, conducted in 2005-2006 (response rate 62%). Exposures were income and educational attainment; outcome was patient report of severe hypoglycemia. To test the association, we used multivariable logistic regression to adjust for demographic and clinical factors.

Results—14,357 patients were included. Reports of severe hypoglycemia were common (11%), and higher in low-income vs. high-income (16% vs. 8.8) and low-education vs. high-education (11.9% vs. 8.9%) groups. In multivariable analysis, incomes of less than \$15,000 (OR 1.51 95%CI 1.19-1.91), \$15,000-\$24,999 (OR 1.57 95%CI 1.27-1.94), and high school or less education (OR 1.42, 95% CI 1.24-1.63) were associated with increased hypoglycemia, similar to insulin use (OR 1.44 95%CI 1.19-1.74).

Conclusions—Low income and educational attainment are important risk factors for hypoglycemia.

Keywords

Socioeconomic factors; hypoglycemia; diabetes mellitus; vulnerable populations

Diabetes mellitus type 2 (DM-T2) is a common problem in outpatient medicine, with over 25 million diabetes patients in the United States.¹ Managing hyperglycemia is a key part of care for diabetes patients, and is a target of quality measures. Although glycemic control can

improve long-term outcomes and avert some complications of diabetes,^{2, 3} intensive treatment can increase the risk of hypoglycemia,⁴ a dangerous complication most common in patients with the lowest and highest hemoglobin A1c (HbA1c) levels.⁵ Hypoglycemia is associated with loss of consciousness and hospitalization,⁶ as well as dementia.^{7, 8} Further, as indicated by the ACCORD Trial,⁹ those who develop hypoglycemia may be at high risk of other adverse events. Recognizing these factors, the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) recently announced joint guidelines on glycemic control¹⁰ calling for careful individualization of HbA1c targets for patients. Appropriate individualization requires careful understanding of both the possible benefits and likely harms for each patient. Special guidelines have been developed for older diabetes patients,¹¹ given their particularly high risk of adverse events. Other factors, such as depression¹² and chronic kidney disease (CKD),¹³ are known to increase risk for hypoglycemia, and appropriate clinical care for diabetes patients with these conditions includes consideration of the tradeoffs between expected benefits and harms.^{14, 15} In contrast to these clinical and demographic factors, whether hypoglycemia is associated with socioeconomic status (SES), as indicated by income or education, is less studied.

As part of the Diabetes Study of Northern California (DISTANCE), we sought to determine if hypoglycemia is more common in those with low SES. Drawing from conceptual models of diabetes care¹⁵ and health services utilization¹⁶ which posit socioeconomic resources as factors that enable safe and effective diabetes management, we hypothesized that lower levels of these resources, as indicated by low income and education, would be associated with increased hypoglycemia.

Methods

Study setting and participants

DISTANCE was conducted among patients in the Kaiser Permanente Northern California (KPNC) diabetes registry (survey instrument available at <http://distancesurvey.org>).¹⁷ We enrolled an ethnically stratified random sample of adult patients aged 30–75. Their survey responses were then linked to comprehensive clinical (including laboratory and prescription) and health service utilization data in the KPNC database. The survey was conducted in English, Spanish, Mandarin, Cantonese, and Tagalog and completed by 20,188 patients (response rate 62%). Further details of the survey rationale, design, and sampling procedure have been previously published.^{17, 18} This study was approved by the institutional review boards at the Kaiser Foundation Research Institute and University of California, San Francisco. Data collection took place from May 2005 until December 2006.

Measures

Our outcome of interest was a self-report of one or more episodes of severe hypoglycemia in the 12 months prior to the survey response. Specifically, the measure identified severe hypoglycemia as a “low blood sugar reaction such as passing out or needing help to treat the reaction.” This item was derived from the previously validated Diabetes Care Profile¹⁹ and is similar to hypoglycemia reporting items used in landmark diabetes trials such as UKPDS²⁰ and ACCORD,²¹ and corresponds to the language recommended by the joint

consensus report of the ADA and Endocrine Society in order to diagnose severe hypoglycemia.²² In addition, we have previously reported that a positive response to this item is associated with an odds ratio of 19.0 for hypoglycemia hospitalizations over the preceding year and that the overall occurrence of severe hypoglycemia in this cohort is 11%.¹⁸

In order to consider distinct components of socioeconomic status, and consistent with current recommendations,²³ we used two separate markers for SES, each of which served as our exposure of interest in separate models. The first was self-reported annual household income (less than \$15,000; \$15,000–24,999; \$25,000–34,999; \$35,000–64,999; \$65,000 or more), conditioned on assets and household size (presence or absence of more than \$10,000 in assets; total number of people in household). Secondly, we used educational attainment, categorized as high school diploma or less, some college, or college graduate or higher.

Analysis

We performed unadjusted analyses to determine the prevalence of severe hypoglycemia stratified by income category. We then specified multivariable logistic regression models to control for potential confounders, one using income as the independent variable, and one using educational attainment. In both models, we controlled for the demographic variables of age and gender. Self-reported race/ethnicity can indicate culture history and differential exposure to social disadvantage, and primary language is one indicator of immigration and acculturation. Because we felt these were important factors to consider in understanding health service delivery and health outcomes,¹⁶ we included these potential confounders of the SES and hypoglycemia relationship in our adjusted analyses. We also controlled for a number of clinical factors that may be associated with hypoglycemia, including HbA1c, renal function, duration of diabetes, medication use (metformin only, secretagogue only, mixed oral medications, or insulin alone or in combination with other medications), self-monitoring of blood glucose (SMBG), presence of dementia, and history of cerebrovascular accident (CVA). After fitting our primary model, we fit two additional models in order to explore ways in which low income and hypoglycemia may be associated. Due to an inability to evaluate temporal ordering, this analysis was only exploratory, but we did consider two factors that could serve as potential mediators within our conceptual model of the relationship between SES and hypoglycemia. Given prior work¹⁸ that demonstrated a relationship between low income, low health literacy, and hypoglycemia, we included health literacy, as indicated by report of lack of confidence in filling out forms. Because low income can impair resources available for medications, we also included self-reported difficulty in filling prescriptions due to cost.

Models accounted for the ethnically stratified random sampling design with expansion weights. We controlled for survey non-response using the Horvitz-Thompson approach.²⁴ We also accounted for item non-response with multiple imputation, performed using the PROC MI procedure in SAS with Markov Chain Monte Carlo simulation, to avoid introducing bias caused by non-random item non-response.²⁵

Descriptive and regression analyses were conducted using STATA version 10 (College Station, TX), and multiple imputation was completed in SAS version 9.2 (Cary, NC).

Results

We received 20,188 survey responses (response rate 62%). From these, we excluded 3,438 patients who were not under pharmacological treatment for type 2 diabetes and another 2,393 who completed only a short version of the survey lacking relevant information about our outcome of interest. The remaining 14,357 patients were included in our analysis. The mean age of our sample was 58 years (SD 10 years), and was 49% female. The sample was 23% Asian, 22% White (non-Latino), 18% Latino, 17% African American, and 20% mixed/other. The mean HbA1c was 7.6% (SD 1.6). Seventeen percent of respondents had household income below \$25,000 annually, and 33% had income of more than \$65,000. Forty-three percent of respondents reported high school diploma or less education, while 31% were college graduate or higher. Full demographics are presented in Table 1.

In unadjusted analyses, lower annual income was associated with greater frequency of hypoglycemia, with 16.2% reporting hypoglycemia among those with incomes less than \$15,000, 16.0% with incomes of \$15–24,999; 10.4% with incomes of \$25–34,999; 10.8% with incomes of \$35–64,999, compared with only 8.8% of those with incomes greater than or equal to \$65,000 (Cochran-Armitage test for trend, $p < .001$). Similarly, lower levels of educational attainment were also associated with an increased frequency of hypoglycemia: 11.9% of those with high school diploma or less education reported hypoglycemia, compared to 8.9% of those with a college degree or higher ($p < .001$). Hypoglycemia remained significantly associated with income and educational attainment in adjusted models (see Table 2).

To put in perspective the risk of hypoglycemia associated with having the lowest (relative to the highest) income (OR 1.51 95%CI 1.19-1.91) and educational attainment (OR 1.42, 95% CI 1.24-1.63), we calculated the increased hypoglycemia prevalence faced by those with two known clinical risk factors. For those using insulin, compared to metformin only, the OR was 1.44 (95%CI 1.19-1.74), and for those with an estimated glomerular filtration rate (eGFR) 30-60ml/min, which corresponds to CKD Stage 3 or 4, compared with eGFR > 60 ml/min, the OR was 1.12 (95%CI 0.98-1.28).

In exploratory analyses, models that included both health literacy and difficulty in filling prescriptions due to cost, in addition to the above covariates, still demonstrated a significant and independent association between hypoglycemia and income (less than \$15,000 OR 1.36 95% CI 1.07-1.72; \$15–24,999 OR 1.45 95% CI 1.17-1.79; \$25–34,999 OR 1.25 95% 1.03-1.51 CI; compared with income more than or equal to \$65,000) and between hypoglycemia and education (high school diploma or less OR 1.29 95% CI 1.12-1.49; compared with college degree or higher).

Discussion

Diabetes patients, even those in the highest income and education groups, commonly reported the occurrence of severe hypoglycemia events. These events represent a considerable safety risk and have an important impact on patient quality of life.²⁶ Both low income and low educational attainment are significantly associated with increased

prevalence of hypoglycemia events, even after adjusting for the demographic and clinical factors that clinicians typically weigh when prescribing diabetes treatment.¹⁰ Guidelines recommend that clinicians carefully consider the increased risk for hypoglycemia in a patient initiating insulin therapy or in a patient with poor kidney function.^{13, 27} Since the strength of association we observed is similar to that of commonly considered clinical risk factors for hypoglycemia such as insulin use, it seems reasonable for clinicians to consider social risk factors as well. We observed an association between income and hypoglycemia among groups well above the federal poverty level (\$20,000 for a family of four in 2006²⁸). While we present our findings in categories for ease of interpretation, our data suggest the association between hypoglycemia and income may be linear across a range of incomes, and that it is not only the most disadvantaged who may be at increased risk.

In order to understand how low SES may be related to increased hypoglycemia, we began with a conceptual model that drew from descriptions of both clinical diabetes care¹⁵ and health services utilization in vulnerable populations.¹⁶ We viewed educational attainment and income as indicators of resources that enabled safe and successful diabetes management, and hypothesized that groups with lower levels of these SES indicators would experience and thus report more hypoglycemia, a negative health outcome of diabetes care. Social structural issues, such as immigration and acculturation are deeply interrelated with education and income. Unfortunately, we were not able to disentangle, or even describe in detail, the complicated interactions between these important factors in this cross-sectional analysis, although our regression analyses do adjust for language, one important indicator of acculturation, along with self-reported race/ethnicity.

Similarly, we were also unable to test causal pathways between SES and hypoglycemia because we could not evaluate temporal ordering. However, previous work suggests several possible mediators, some of which we were able to examine in an exploratory way in this study. Prior work in this dataset revealed a significant association between low health literacy and hypoglycemia,¹⁸ and our data did show a modestly diminished association between SES and hypoglycemia when health literacy is included in our regression analysis. The relationship between lower educational attainment, lower health literacy, and hypoglycemia is consistent with our conceptual model, where health literacy serves as an enabling factor for safe diabetes management. The same can be said for medication underuse resulting from difficulty filling prescriptions due to cost. Poor glycemic control due to medication underuse could lead to increased medication doses, which may then prompt hypoglycemia during intermittent use. Finally, one variable unavailable to us in this study is food insecurity. Since food insecurity is known to be associated with both low SES and hypoglycemia,^{29, 30} it may be an important avenue for future work, especially as a significant association between SES and hypoglycemia remained unexplained by the inclusion of health literacy and difficulty filling prescriptions. In addition, factors that are more common in low SES patients, such as more severe diabetes^{5, 31}, decreased social support³²⁻³⁵, and higher rates of depression^{12, 36} may explain some of the association between lower income/educational attainment and hypoglycemia. The latter two may be particularly important for explaining increased hypoglycemia at relatively higher income levels, where material deprivation or cost-related medication underuse may be less common.

Our results are consistent with and expand upon those of prior studies. The ACCORD study²¹ suggested an increased of hypoglycemia in those with low educational attainment, but this was in a highly selected, clinical trial group. Demonstration of this association in a real-world cohort provides clinicians useful information. Prior population studies have also suggested increased risk of hypoglycemia with lower socioeconomic status (SES),³⁷⁻³⁹ but these studies had several limitations. Chiefly, they relied on indicators of health services utilization for hypoglycemia, such as emergency department visits. Because episodes of hypoglycemia may not come to medical attention, this approach may under-ascertain events. Furthermore, many of these studies lack the ability to adjust for relevant confounders, especially clinical variables and were conducted outside the United States, in settings with health care delivery systems that differ markedly from the American model. Finally, several of these studies were conducted prior to the current intensive, “treat-to-target” strategy of glycemic control.

We assessed severe hypoglycemic events using an instrument similar to that used in the UKPDS and ACCORD studies. The UKPDS reported an annual occurrence of severe hypoglycemia of 0.6%,²⁰ and ACCORD²¹ reported 5.05 events per 100 person-years at risk in the intensive treatment arm and 1.51 events per 100 person-years at risk in the standard arm. We observed an even higher occurrence of self-reported severe hypoglycemia, 9% in the highest income group, and 16% in the lowest. Because hypoglycemia was assessed similarly in all three studies, we suspect that the higher rates of hypoglycemia in the DISTANCE Study cohort reflect the true risk in an ethnically diverse, real-world diabetes cohort, relative to more selective trial cohorts. Population-based studies in Finnish⁴⁰ and German⁴¹ diabetes patients reported similarly high population rates of hypoglycemia. Glycemic targets based on data from highly selected populations with low rates of hypoglycemia may overestimate net clinical benefit for real-world patients.

Strengths of this study include its large, ethnically diverse sample taken from an integrated health care delivery system with excellent record keeping and mechanisms for chronic disease management. To our knowledge, the DISTANCE study includes the largest sample of self-reported hypoglycemia in a U.S. diabetes cohort. The survey instrument was administered in five languages, increasing generalizability. Our validated self-report measure of hypoglycemia allowed for increased sensitivity compared with prior studies that used only health-service utilization data, while retaining confidence that reported events are actual episodes of hypoglycemia.

This study has several limitations. Because of its cross-sectional design, conclusions about causality cannot be drawn, and thus our understanding of mechanism remains limited. Although we did link our self-report hypoglycemia measure to clinical data, showing an OR of 19.0 for emergency department visits or hospitalization for hypoglycemia over the preceding year among those reporting hypoglycemia compared to those who do not,¹⁸ we did not require documentation of blood glucose level at time of symptoms, which could result in some symptoms that were not caused by hypoglycemia being reported as such. Complete surveys or response to certain items are often missing in survey research, and they were in this case. Though our response rate was 62%, when posterior exclusions, such as eligibility, are considered, less than 50% of the original survey sample was included in this

analysis. However our Horvitz-Thompson weighting and multiple imputation approach allowed us to control for bias introduced by survey and item non-response. Compared with a complete case analysis, multiple imputation is the preferred approach for dealing with item non-response in a large survey dataset.²⁵ Next, the patients in DISTANCE were enrolled in an integrated health care delivery system. Current national estimates suggest that over 90% of the patients with diabetes in the U.S. population have some form of insurance.⁴² Thus our findings should be widely generalizable to insured patients with diabetes. Moreover, this study population is broadly representative of the population of northern California.⁴³ However, this health care setting is different from many safety net systems in which low-SES and culturally diverse patients receive care. Thus our findings may not apply to the most vulnerable population of uninsured patients with diabetes. Finally, this was an observational study, with no intervention, and thus we do not know if this observed socioeconomic gradient in hypoglycemia is modifiable.

Regardless of whether socioeconomic status has a causal relationship with hypoglycemia, however, understanding how it is associated with hypoglycemic risk is a critical component of safely managing hyperglycemia in vulnerable diabetes patients. Further work is needed to inform management strategies. In particular, there is a need for testing multifaceted approaches to hypoglycemia reduction that are sensitive to issues faced by vulnerable patients. Such interventions might include provider education about increased hypoglycemia risk and guidance for selecting medications less likely to cause hypoglycemia. In addition, they could include patient education material appropriate for those with low literacy, nutritional supplementation to address food insecurity, and pharmacy benefit redesign to address cost-related medication underuse. While what we propose is more extensive, diabetes management programs specifically targeted to vulnerable patients have already shown some benefits.⁴⁴ In the interim, we suggest that clinicians continue to build on what is already known about hypoglycemia risk. Clinicians should be aware of the known risks and barriers that come with low health literacy and food insecurity, and incorporate this knowledge into their patient counseling. Ensuring that patients with low health literacy have an adequate understanding of their medication regimen is another vital step.

Given the potential for increased hypoglycemia among vulnerable diabetes patients, we suggest clinicians consider social risk factors in addition to clinical risk factors when intensifying glycemic-lowering therapies. Explicit attention to this issue will help ensure that the benefits of glycemic control accrue safely to all patients.

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Table 1

Demographics and Clinical Characteristics (n = 14,357)*

Characteristic	n or Mean (% or standard deviation)
Female gender	7,068 (49)
Age (years)	58 (10)
Race/Ethnicity (self-reported)	
African-American	2,417 (17)
Non-Hispanic White	3,202 (22)
Latino/a	2,632 (18)
Asian	3,265 (23)
Other/Mixed	2,841 (20)
Household annual Income	
>\$65,000	4,673 (33)
>\$35–64,999	3,728 (26)
>\$25–34,999	1,472 (10)
>\$15–24,999	1,080 (8)
<\$15,000	1,305 (9)
Highest Educational Attainment	
High School Diploma or Less	4610 (43)
Some College	2812 (26)
College Graduate or Higher	3297 (31)
Hemoglobin A1c %	7.6 (1.6)
Medication Type	
Insulin	3,142 (22)
Metformin only	2,727 (19)
Secretagogue only	2,284 (16)
Mixed Oral Meds	6,205 (43)
Diabetes Duration (years)	10 (8)
Estimated glomerular filtration rate (eGFR) in ml/min by MDRD equation	
eGFR >60	9,156 (64)
eGFR 30–60	3,037 (21)
eGFR <30	354 (3)
Self-Monitoring of Blood Glucose (SMBG)	6,934 (48)
Dementia	159 (1)
History of Stroke	382 (3)
Low Health Literacy	4,539 (32)
Limited English Proficiency	1,386 (10)

* not all variables have N=14,357 due to missingness.

Table 2

Multivariable logistic regression results for odds of reporting hypoglycemia *

	Model 1 (Income)		Model 2 (Educational Attainment)	
Characteristic	OR	95% CI	OR	95% CI
Yearly Income				
<\$15,000	1.51	1.19–1.91	--	--
\$15–24,999	1.57	1.27–1.94	--	--
\$25–34,999	1.32	1.09–1.60	--	--
\$34–64,999	1.06	0.92–1.23	--	--
>\$65,000 (reference)	1.0	--	--	--
Educational Attainment				
High School Diploma or Less	--	--	1.42	1.24–1.63
Some College	--	--	1.02	0.88–1.19
College Graduate or Higher (reference)	--	--	1.0	--
Age Group (years)				
30-49 (reference)	1.0	--	1.0	--
50-59	1.01	0.87–1.17	0.96	0.83–1.11
60-69	0.83	0.70–0.97	0.80	0.68–0.93
70+	0.77	0.63–0.94	0.76	0.63–0.92
Race/Ethnicity				
Caucasian (reference)	1.0	--	1.0	--
African-American	1.33	1.15–1.53	1.43	1.25–1.65
Latino	1.35	1.16–1.58	1.47	1.26–1.71
Asian	1.28	1.09–1.51	1.36	1.15–1.60
Filipino	1.92	1.63–2.25	2.35	2.00–2.76
Multi-/Other	2.48	2.14–2.88	2.69	2.33–3.11
Male Gender	1.08	0.97–1.20	1.03	0.92–1.14
Assets > \$10,000	0.77	0.67–0.88	--	--
Family Size	1.09	1.04–1.14	--	--
eGFR (ml/min)				
>60 (reference)	1.0	--	1.0	--
60-30	1.12	0.98–1.28	1.10	0.96–1.26
<30	1.74	1.23–2.47	1.72	1.22–2.41
HbA1c (%)				
<7 (reference)	1.0	--	1.0	--
7-8	1.10	0.96–1.26	1.09	0.95–1.25
8-10	1.20	1.03–1.40	1.20	1.03–1.39
>10	1.15	0.94–1.41	1.14	0.93–1.40

	Model 1 (Income)		Model 2 (Educational Attainment)	
Characteristic	OR	95% CI	OR	95% CI
Duration of Diabetes (years)				
0-9 (reference)	1.0	--	1.0	--
10-19	1.01	0.89–1.14	1.00	0.89–1.14
20+	1.11	0.92–1.34	1.11	0.92–1.34
Took Survey in English	0.45	0.38–0.52	0.38	0.33–0.44
Self-monitors Blood Glucose	0.89	0.80–0.99	0.90	0.80–1.00
Hx of Dementia	1.78	1.08–2.93	1.86	1.13–3.04
Hx of Stroke	1.13	0.82–1.56	1.19	0.87–1.64
Diabetes Medications				
Metformin Only (reference)	1.0	--	1.0	--
Secretagogues Only	1.19	1.03–1.39	1.28	1.07–1.52
Mixed Oral Medications	1.26	1.05–1.50	1.20	1.04–1.39
Insulin	1.44	1.19–1.74	1.48	1.23–1.79

*
report odds ratios are adjusted for all covariates in model