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Factors Associated With Type 2 Diabetes Management In Santa Elena, Ecuador

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Abstract

Background: There has been a growing prevalence of diabetes in rural populations in low and middle income countries. Over a third of Ecuador's population lives in rural areas, which tend to experience poorer health outcomes than urban areas. Therefore, the objective of this study was to examine potential risk factors associated with diabetes management in this region.

Methods: A sample of 150 diabetes patients from the Futuro Valdivia clinic in Santa Elena, Ecuador were surveyed and tested for HbA1c. The interview collected data on a variety of risk factors including diet, exercise, eating habits, food insecurity, medication usage, medication adherence, mental health, sleep, and social support. Chi-square tests and multivariate logistic regression analysis were used to identify the risk factors associated with poor diabetes management (HbA1c $\geq$7.0%) in those that had a valid HbA1c reading (n=148). Backwards elimination was used to generate a final reduced model.

Results: Nearly three quarters of the study population had poor glycemic control. 58.8% were female, 85.8% had a grade school education or less, and the mean age was 56.8 years. A majority of patients (78.4%) were taking diabetes medication and over half paid for their medications out of pocket. Over one-third (37.7%) reported severe food insecurity. Adjusted odds of severe food insecurity (OR= 3.45, 95%CI 1.05, 11.37) and using medications (OR=6.02 95%CI 1.48, 24.57) were greater in those with poor diabetes management after adjusting for covariates.

Conclusion: Findings indicate that individuals with severe food insecurity and those that use diabetes medications have higher odds of poor management. The high proportion of patients with poor diabetes management signals a need for better care and support for self-management of diabetes in this region of Ecuador.

Introduction

The increasing burden of type 2 diabetes is a concern for many Latin American countries and Ecuador is no exception to this trend.[1] Type 2 diabetes prevalence has been steadily increasing since the 1980s, and as of 2014, the diabetes prevalence in Ecuador was 5.71% in adults 20-79 years old.[2, 3] Especially concerning is the data suggesting that the prevalence of diabetes in rural regions is growing globally, and is occurring at a faster rate in low and middle income countries (LMICs) than in high income countries (HICs). [4] As of 2013, 37% of Ecuador's population is living in rural areas, and there is evidence that similar regions encounter barriers to appropriate diabetes care and management, such as increased distance to clinics and lower quality of care.[5, 6] It is important to understand the challenges that individuals with diabetes face in these regions when managing this disease.[7]

Effective diabetes self-management is a result of appropriate dietary intake, exercise, and adhering to necessary medication regimens. Diabetes control is measured through levels of glycosylated hemoglobin (HbA1c). Levels under 7.0% are generally considered appropriate management for patients with type 2 diabetes, and this is also the target HbA1c level recommended by the Latin American Diabetes Association.[8] High HbA1c levels have consistently proven to be associated with increased risk of morbidity and mortality in long-term studies.[9-11]

Numerous factors play a role in type 2 diabetes management, and these factors may vary between different populations.[12, 13] It is important to establish the key risk factors for inadequate management in specific populations in order to target both population and individual level interventions most effectively. Diabetes management in rural regions of low and middle income countries has been understudied; to our knowledge, this is the first study on diabetes management in rural Ecuador. .

Literature Review of Risk Factors

Diet and Exercise

Healthy dietary habits and physical activity have been shown to have clear beneficial effects on both the prevention and management of type 2 diabetes.[14-16] Recent studies suggest a lowering of HbA1c by 0.5%-1.1% through changes in diet alone.[15] While much research has been done on the effect of individual nutrient intakes and different dietary patterns, it seems that overall dietary quality is more important than quantity. The American Diabetes Association recommends individuals with diabetes eat more whole grains, fruits, vegetables, legumes, and nuts; fewer refined grains, red or processed meats, and sugar-sweetened beverages; and drink alcohol in moderation.[17] Diets low in carbohydrates and with a low-glycemic load have shown clear benefits for glycemic control in individuals with diabetes.[15] For overweight and obese individuals, weight loss from low-energy diets has also been effective in reducing HbA1c levels.[18-20] However, there is increasing evidence that low-carbohydrate diets are more effective at lowering HbA1c levels than low-fat diets in overweight and obese individuals despite similar weight loss.[21-24]

Physical Activity of any type has been shown to lower blood glucose,[15, 25] with a combination of aerobic and resistance exercise being most effective.[26] Many studies have examined the efficacy of lifestyle interventions involving a combination of diet and exercise to prevent diabetes onset and improve diabetes control. Studies such as the Look AHEAD trial and the Diabetes Prevention Program (DPP) have shown that a combination of increased physical activity and dietary changes focused on lower caloric intake and fat restriction, have effectively decreased HbA1c levels in overweight and obese individuals with diabetes or at risk for diabetes.[27-29]

Lifestyle interventions have not been as well studied globally, however research done so far in low-income settings and rural populations have shown promise. A study in the Dominican Republic that successfully implemented a community health worker-led lifestyle intervention, found a significant decrease in HbA1c levels in adults with diabetes or prediabetes.[30] A study in rural Montana successfully implemented an adapted version of the DPP for overweight adults at risk for diabetes, and found that 62% achieved the 7% weight loss goal.[31] Another adaption of the DPP for a low-income Latino population was also successful, and the intervention showed improvements in HbA1c levels and insulin resistance among adults above 25 years old, at risk for diabetes.[32]

Eating Habits and Food Insecurity

Eating regularly and not skipping meals has been shown to be associated with better diabetes management and lower HbA1c levels.[33] Conversely, an analysis of the Health Professionals study has shown that skipping meals and snacking outside of the three main meals were associated with higher diabetes incidence among men aged 40-75.[34] It should be noted that the type of foods eaten as snacks were not accounted for in this study, therefore the increased risk may be due to increased energy intake.[34] Increased snacking frequencies have been associated with excess energy intake, overweight, and obesity.[35] A study in Brazil sampling individuals over 10 years old from the 2008-2009 Household Expenditure Survey showed that 74% of the study population snacked; many of the snacks were high in fats and sugars.[36] However, healthy snacking can be beneficial, and The American Diabetes Association recommends healthy snacks that are low in carbohydrates to manage diabetes.[15]

In order to plan one's diet, it follows that one must be involved in the decisions behind what one eats. Therefore, the person responsible for the shopping and cooking of foods is expected to have the greatest decision making power over their own diet, and perhaps those of others. If that responsibility lies with the diabetes patient, he or she may have greater control of their diet and diabetes management. Not many studies have been undertaken to support this hypothesis. A study in Denmark followed newly-diagnosed diabetes patients for 19 years, and found that women who cooked for themselves less than once a week were at an increased risk of diabetes-related death.[37] Men showed no significant difference in diabetes-related deaths between those who were and were not involved with cooking.[37]

Control over one's diet and management of diabetes is also affected by food insecurity. Uncertainty of food availability may lead to changes in eating habits such as substituting costlier but healthier items for cheaper high-calorie foods. Uncertainty about one's financial state may lead one to skip meals or replace meals with snacks.[38] Food insecurity may also affect medication use, as a study in California of adults with type 2 diabetes has shown.[39] The findings of this study in California showed that food insecurity was associated with delays in filling prescriptions after adjusting for income, insurance status, previous access to care, and health status.[39] Sacrifices in dietary quality and increased levels of psycho-emotional stress due to food insecurity may lead to poor health outcomes for those with diabetes. Studies on individuals with diabetes, including one on Latinas aged 35-60 years, and a second on low-income adults above age 18, have shown that food insecurity is associated with higher levels of HbA1c.[40, 41]

Medications and Adherence

When lifestyle interventions alone cannot achieve the glycemic goals for a patient, oral medication is a common and effective treatment option. Metformin is the preferred first option for oral diabetes medication among physicians in Latin America, and may be combined with additional oral anti-glycemic medication and/or insulin as disease severity increases.[42] Medication adherence plays an important role in managing diabetes as it has been shown to lead to better glycemic control.[43, 44] Often times non-adherence is a result of forgetfulness,[45] but non-adherence can also be influenced by patient's poor understanding of the treatment and its benefits, side effects, prohibitive costs, regimen complexity, and the patient's emotional state.[46] Low-income populations may have a higher likelihood of medication non-adherence due to financial barriers, lack of family or social support, mental health issues, or misconceptions about the medication.[47-49]

Diabetes management and HbA1c may also be affected by comorbidities such as obesity, hypertension, cardiovascular disease, depression, and microvascular complications. According to a study in nine Latin American countries by *Lopez Stewart et al.,* comorbid conditions were present in 86% of diabetes patients.[42] Those with comorbidities may also take medications for the treatment of those conditions. Use of additional medications can interfere in the management of diabetes and increase HbA1c levels due to the reduced efficacy of diabetes treatment.[50] In general, challenges arise in managing diabetes and any additional illnesses when individuals with diabetes have comorbidities.[51-53]

Mental Health, Sleep, and Social Support

There is growing evidence that depression is significantly associated with an increased risk of developing type 2 diabetes and vice versa. A systematic review of the evidence on the relationship between type 2 diabetes and depression reported that the prevalence of depression is almost twice as high in those with diabetes;19.1% (range 6.5–33%) in comparison to 10.7%, (range 3.8–19.4%) for those without diabetes.[54] The nature of the relationship is unclear, but there is increasing evidence that there is bi-directionality between depression and diabetes. Depression may develop as a consequence of diabetes due to the stress and psychological burden of chronic disease in addition to the higher level of care needed to manage the disease.[55] However, there is also evidence that depression is a risk factor for diabetes. One current hypothesis suggests that the biochemical changes that occur in the body as a result of depression may increase risk of diabetes.[55] A second hypothesis suggests that depression may lead to behavioral changes such as decreased physical activity or increased alcohol consumption that may ultimately increase one's risk of diabetes or poor diabetes management.[55] Few studies have looked at the prevalence of diabetes and mental health comorbidities in LMICs, but the limited body of evidence suggests that the prevalence of depression in individuals with diabetes is higher in LMICs than in HICs.[56] Studies from urban areas of Mexico documented prevalences ranging from 27.4% to 63.0%, and one study in the rural regions of Mexico found that 40.5% of the population with diabetes was at risk for depression.[56] With the increasing number of diabetes cases in LMICs, it is important to better understand the nature of the relationship of this condition with depression in these countries.

Quantity and quality of sleep has been shown to play a role in both the risk of developing type 2 diabetes and the management of diabetes. A recent meta-analysis of ten prospective studies conducted in the US, Europe, and Australia found that amount of sleep has a U-shaped relationship with diabetes incidence in adults. The findings suggest that 7-8 hours of sleep per night is the optimal amount for prevention of diabetes incidence.[57] In addition, studies have found that individuals with perceived sleep deprivation or lower sleep quality as determined by the Pittsburgh Sleep Quality Index (PSQI) survey had significantly higher HbA1c levels; this relationship was found in individuals with diabetes and those at risk of developing diabetes.[58-60] Conditions such as obstructive sleep apnea have also shown an association with poor diabetes management.[61, 62] Evidence suggests that obstructive sleep apnea and diabetes have a bidirectional relationship, with each increasing the risk of the developing the other.[62] While the mechanisms between sleep status and HbA1c levels are still debated, there is good evidence that sleep is an important predictor of diabetes management.

There is still conflicting evidence on the relationship between social support and diabetes management.[63] Both family support and composite measures of support have shown associations with lower HbA1c levels, improved adherence, and better quality of life.[48, 63, 64] Higher levels of social support have also been associated with lower mortality and fewer complications in individuals with diabetes.[64, 65]However, intervention trials aiming to increase peer or family social support have shown weak results in improving diabetes outcomes, including glycemic control.[66, 67] Social support has been hypothesized to aid diabetes management by providing support for health-related issues and stress, aiding with treatment adherence, and providing a buffer during financial troubles.[63, 68] Social support is also thought to be a modifier for depression and self-management behaviors on overall diabetes management and HbA1c levels, and has been documented in Latin American populations.[68, 69] It is also important to consider gender differences in social support, as several studies on adults with diabetes have shown that social support can have different associations with glycemic control as a function of gender.[63, 64] However, further studies are needed to clarify the relationship between gender, social support, and diabetes management [63, 64].

Objective

This study aims to examine potential risk factors for poor diabetes management, as measured by HbA1c, in the coastal, rural towns of the Santa Elena province of Ecuador. In addition, we developed this study in partnership with the clinic, Futuro Valdivia, with the needs of the community in mind. The staff at Futuro Valdivia wanted to have a better understanding of what factors most strongly influence patients in the management of their diabetes, in the hopes that they may be able to better serve their diabetes patient population. Diabetes is also a topic of interest for the local population, as it was found to be the third highest concern for the residents of a neighboring town, Manglaralto, in a needs assessment conducted in 2013.[70]

Study Methods

Location and Participants

Futuro Valdivia is a private clinic located in the coastal town of San Pedro, Ecuador located in the Santa Elena province. The clinic aims to offer quality primary care for both children and adults, that is affordable for the low-income population in the surrounding areas. The clinic attracts patients who live well beyond the borders of its neighboring towns.

According to the 2010 census of the Santa Elena, there is a 5.2% rate of illiteracy in the province, and the majority of the population lives in rural areas.[71] A study by Neira-Mosquera et al. found that the mortality rate between 2001-2008 in the Guayas province (part of which later became the Santa Elena province, the location of this study) from type 2 Diabetes related causes was 31.7 deaths/100,000 individuals, the highest of any province.[72]

Procedures

Between May and July 2014, a total of 150 patients were interviewed and tested for HbA1c, our indicator of diabetes management. Adult patients who had a medical record at the clinic and a diagnosis of type 2 diabetes were eligible for the study. The survey was piloted on the local clinic staff (n=4) to be certain that the survey questions were easily understood in the context of the local culture and language.

A complete list of diabetes patients and their addresses was provided by the clinic to the research team and was used to find and visit patients at their homes to recruit for the study. New and former patients who happened to visit the clinic during the study period were also recruited for the study. The interviews were conducted in Spanish in the Futuro Valdivia clinic or at the subject's home. Following the survey, approximately 0.5 mL of blood was collected in EDTA coated tubes from a finger prick. Blood samples collected at the clinic were tested immediately following blood collection (n=23). If the blood sample was collected at the participant's home, it was transported on ice until the research staff was able to return to the clinic and conduct the HbA1c test (n=125). In all cases transportation time was less than 6 hours after collection. HbA1c levels were tested using Siemens DCA 2000 System for HbA1c testing, following the manufacturer's protocols.

Ethical Considerations

This study was approved by the Yale University Institutional Review Board. There was no board or committee involved in research ethics associated with the study clinic, therefore written permission to conduct the study was obtained from the Futuro Valdivia clinic director and owner. The purpose of the study, patient confidentiality, and the option to refuse to participate in any part of the study was explained verbally in Spanish to all participants prior to conducting the survey and blood draw. Verbal consent to participate in the study was required from the subject before proceeding with any study procedures. The HbA1c test was offered free of charge, and there was no cost or incentive to participate in the study, A small button pin was offered as a gift of appreciation after the interview. All participants were assigned a study ID and no names were used during the data collection or analysis.

Measures

Independent variables of interest were measured through scales or questions in the administered survey. All scales used in the survey have been used and validated in previous studies. Many of the survey questions were used or modified from the intake survey used in the DIALBEST study, with permission from the lead investigator.[73] The division of each measure into categories for analysis was dependent on the number of complete responses available for each measure as well as the distribution of responses.

Diet was measured using the Individual Dietary Diversity Score (IDDS) using the methods explained by FAO.[74] This score has been shown to correlate with adequate nutrient intake in all ages.[74] While not as detailed as a food-frequency questionnaire, similar dietary diversity scores have been shown to be correlated with diabetes incidence [75]. The IDDS requires a 24-hour recall of foods eaten from the day preceding the interview. These food items are then categorized into major food groups. The food groups include the following: cereals; white tubers; vitamin A rich vegetables; dark green leafy vegetables; other vegetables; vitamin A rich fruits; other fruits; organ meats; flesh meats; eggs; fish and seafood; legumes, nuts, and seeds; milk and milk products; oils and fats; sweets; spices, condiments, and beverages. Eating any number of food items that can be categorized in a major food group gives that particular food group a score of 1. Not having eaten any foods from a food group is scored as zero. The total score is the sum of the scores in the individual food groups. Scores range from 1-16 with higher scores indicating more diversity and therefore a higher quality diet. Currently there is no international consensus on which food groups should be included in the individual level score, but this analysis will use a total score of all 16 food groups.[74] This variable was divided into tertiles for analysis.

Amount of physical activity was measured using the Stanford Patient Education Research Center's Spanish Exercise Behaviors Scale. This short scale has been validated in Spanish (test-retest, r=0.92) in 5 locations in the US and Venezuela, [76] and it approximates the time spent doing physical activity in half hour intervals. This scale was analyzed as a categorical variable using tertiles. The Cronbach's alpha calculated for this study for the aerobic activity portion of this scale was quite low (.34), so caution should be taken when drawing conclusions from these data.

Sleep adequacy was determined using two simple survey questions: "On average, how many hours do you sleep each night?" and "On average, do you feel that you get enough sleep?" These were analyzed as a continuous and binary variable, respectively.

The Spanish version of the Patient Health Questionnaire (PHQ-8) was used to measure depression. This scale has 8 items and is scored from 0 to 24, where a score greater than 10 was used as the cutoff for depression, as recommended by the creators of the questionnaire. Internal validity for the PHQ-8 in this study achieved an adequate Cronbach's alpha of 0.84.

Medication Adherence was measured using the 4 question Morisky Scale, and was analyzed as a binary variable. This scale has been used in numerous research studies and has proven to be a simple and valuable tool. Previous psychometric analysis has found that Cronbach's alpha = 0.61, sensitivity = 81%, and specificity= 44%.[77] However, this study found that internal consistency was lower than the accepted value of 0.7, and therefore interpretation of the data must take this into consideration (Cronbach's alpha = 0.47). This measurement was only taken if the subject indicated that they were prescribed medications for diabetes (both oral and/or injectable medications).

Food Security was measured using the Latin American and Caribbean Household Food Security Scale (ELCSA), a scale that has been validated in Spanish in Mexico.[78] For this study, internal validity was high with a Cronbach's alpha coefficient of 0.94. This variable was divided into two categories using a cut-point that has been used in previous studies: mild food insecurity 0-10, severe food insecurity 11-16. [79]

Social support was measured using a combination of two established and validated scales, the Multidimensional Scale of Perceived Social Support (MSPSS) and the Multidimensional Diabetes Questionnaire (MDQ). Cronbach's alpha for these two scales were previously found to be 0.91 and 0.77, respectively.[80, 81] The combined scale previously had a Cronbach's alpha of 0.87, [69] and in this study also had a high internal consistency with a Cronbach's alpha of 0.81. This 11-item questionnaire has three-point response options, and is scored on a range from 0 to 22. These responses were categorized into tertiles for analysis.

Socio-economic status (SES) was measured using ten household belongings as a proxy for household wealth. Income was not probed for as it was expected that the information would be difficult or sensitive to report by some respondents. Each item was given a standardized weight based on the frequency that each item was present in the study population. This weight was then applied to each items score. Each belonging was assigned a score of one if the item was available in the household, and assigned a score of 0 otherwise. An additive score that could range from 0 to 1 was computed for each subject, and was categorized as low or high SES using the median value of the study population as a cut-off point.

In addition to the independent variables of interest described above, data on confounding factors were measured and recorded. These include body mass index (BMI), number of comorbidities, smoking status, drinking habits, if the patients uses diabetes medications, number of additional medications taken, education, employment status, age, gender, form of payment for medications, and location of blood draw. Height and weight measurements for BMI were taken by the research staff at the time of the survey and blood collection. In the case of 32 patients, BMI could not be measured at the time of the survey and were recorded as missing. Reasons for missing height and weight were due to lack of equipment, lack of a flat surface, or the patient's inability to stand.

Data Analysis

All analyses were carried out using SAS analytic software (SAS software v. 9.3, Cary, NC). Comparisons between those with poor diabetes management (HbA1c > 7), and those with adequate diabetes management (HbA1c $\leq$ 7) were conducted using t-tests for continuous variables, and chi-square tests or Fisher's exact test for categorical variables (Table 1). All variables with p-values under 0.20 in the bivariate analysis were included in the fully adjusted logistic regression model. Backwards elimination was used to create a reduced and final model which is presented along with the fully adjusted model in Table 3. Age, gender, education, and BMI were included in both the full and adjusted model regardless of significance because these are essential demographic and clinical measures. Because there was a difference in procedures and in time between blood draw and the testing of the blood sample depending on the location of the blood draw, this variable is controlled for in the full and adjusted model. Despite its significant Chi-square p-value, the employment variable was not included in the adjusted models due to multicollinearity with gender.

Only subjects with complete data on all variables of interest were included in the regression models, lowering the total number of patients analyzed to 105. Loss of data from the analysis was mostly due to missing information for BMI and medication payment. Chi-square tests of missing and non-missing data by age and SES showed no significant difference (p=0.45 and p=0.93, respectively), indicating that attrition bias was not present.

Results

Descriptive statistics

Of the 150 patients surveyed, we were not able to get a blood sample for two patients, so only the remaining 148 patients that had a valid HbA1c reading, were used for data analysis. A large majority (74.3%) of the surveyed patients had an HbA1c reading above 7.0% and was categorized as poorly managed. The mean HbA1c for the study population was 9.59%. Of the 148 patients, 58.8% were female, 74.8% were married, and 85.8% had elementary school education (6 years of school) or less. The mean age of the study population was 56.8 years old and ranged between 28 and 89 years. The mean BMI was 26.13 kg/m^2, and the average time since diabetes diagnosis was 7.2 years at the time of the survey. A large proportion of the patients were taking oral diabetes medication (78.4%) of which only 3 individuals were also using insulin. Approximately a quarter of the study population was taking additional medications for other chronic conditions. A majority of the subjects were not working (this category includes those who were homemakers, unemployed, or retired), and over half of the study subjects reported paying for their diabetes medications out of pocket.

Bivariate analysis

Of the demographic variables listed in Table 1A, education, employment status and SES were significantly different by adequacy of diabetes management. A significantly greater proportion of poorly managed patients were well-educated (18.2%) in comparison to well-managed patients (2.6%, p=0.02). However, one should be cautious drawing conclusions due to the very small number of subjects (21 individuals) with a higher than elementary education. Among well-managed patients, more than half were not working and had low SES (55.3% and 57.9%, respectively), whereas in poorly managed patients 36.4% were not working and 41.8% had low SES.

Compared to well-managed patients, individuals that were poorly-managed were more likely to have been diagnosed with diabetes over 6 years ago, be overweight (BMI 25-30 kg/m^2), take medications for diabetes, take no other medications for other illnesses, and have their blood drawn outside the clinic (Table 1B). Additionally, a greater proportion of individuals with poor diabetes management have someone else cooking meals for them, severe food insecurity, and fewer hours of sleep a night in comparison to those who are well-managed (Table 1C).

Multivariate analysis

After backwards elimination was carried out, gender, age, education, SES, BMI, diabetes medication use, location of blood draw, and food insecurity remained in the final multivariate logistic model (Table 3). After adjusting for covariates, individuals with severe food insecurity were found to have significantly higher odds of poor diabetes management (OR=3.45, 95%CI 1.05, 11.37). In addition, taking diabetes medications was associated with higher odds of poor management (OR= 6.02 95%CI 1.48, 24.57). While more years of education and location of blood draw outside of the clinic were associated with greater odds of poor management in the bivariate analyses, after adjustment for covariates these associations were no longer significant (Tables 2 and 3).

Discussion

Studies have typically found a high proportion of poorly managed diabetes patients in low-income populations.[13, 42, 82] The results of this study are consistent with prior research as our findings revealed that nearly three quarters of individuals with diabetes who sought care at the Futuro Valdivia clinic are poorly managed. Our findings for this population showed that the key independent risk factors significantly associated with higher odds of poor glycemic control are the use of diabetes medication and severe food insecurity.

Both oral and injectable medications for diabetes have long been known to effectively lower HbA1c levels.[83, 84] Therefore, this study's findings are most likely a result of reverse causality i.e. patients with poor glycemic control are more likely to be using diabetes medications. This same association has been shown to occur in other cross-sectional studies in low income countries.[82, 85] However, it remains clear that the large majority of patients who take medications are also poorly managed, and it is possible that more aggressive treatment such as insulin therapy alone or in conjunction with oral medications is needed for better glycemic control. In the nine Latin American countries surveyed by *Lopez Stewart et al*, insulin therapy was used by 14.5% of diabetes patients.[42] In our study sample population, only three out of 150 individuals (2%) were taking a combination of oral medications and insulin treatment. This difference in the proportion of patients on insulin treatments suggests that some individuals in this study were not using insulin despite a potential need for the medication.

The high proportion of poor-management in patients that reported medication use could also be due to improper adherence. However, this study found no difference in medication adherence between poor and well-managed patients. On the other hand, a true association between adherence and management may have been masked due to social desirability bias or low internal consistency of the Morisky Scale. Longitudinal studies are needed to confirm these hypotheses and to better understand the association between medication use and HbA1c in this population.

Our study's finding that severe food insecurity is associated with higher odds of poor diabetes management is consistent with other studies in both low-income and Hispanic populations.[41, 86, 87] The link between food insecurity and diabetes is not fully understood, however one theory is that food insecurity leads to unhealthy dietary patterns due to food costs. Studies have suggested that food insecure households struggle to buy fruits, vegetables, and other healthy foods due to the greater cost of these items in comparison to processed foods. If food is scarce, it may lead individuals to decrease portions, and replace or skip meals.[38] The inability to buy the necessary foods to maintain a healthy diet is hypothesized to create fluctuations between hyperglycemic and hypoglycemic states, and is one potential mechanism for the association between food insecurity and poor diabetes management.[41] However, many of these studies on the relationship of food insecurity, food access, and diabetes have been conducted in the U.S. or other developed countries,[86-88] and few studies have explored this association in Latin American countries or other LMICs. Food markets, access, and availability may operate differently in LMIC's and rural regions, such as the location of this study. Therefore, more research is needed to understand the connection between food availability and cost, and glycemic control.

A second hypothesis is that food insecurity leads to poor management due to the competing needs for healthy foods and diabetes medication and care. With limited resources, an individual with diabetes may forgo their medication in order to afford adequate food, or they may go hungry or eat unhealthy food to be able to afford their medications. One study in rural, Latino, diabetes patients found that study subjects with food insecurity were also more likely experience cost-related medication underuse and worse outcomes on a composite score of HbA1c, blood pressure, and LDL cholesterol.[89] A second study using National Health Interview Survey data (NHIS), found that nearly a quarter of subjects with any type of chronic illness reported cost-related medication underuse.[90] In our study population, over 55.2% of patients reported paying for medications out of pocket, which could be a potential source of financial strain. If diabetes patients compromise on dietary quality or diabetes medication, the outcome in either case can lead to poor glycemic control.

A third hypothesis is that poverty-related stress reflected in severe household food insecurity may increase the risk of poor glycemic control in diabetes patients. There is evidence to suggest that those in food insecure households experience greater stress and anxiety[91, 92] Psychological stress may lead to several health outcomes that are risk factors for poor diabetes management. These include poor eating behaviors, higher BMI, and metabolic syndrome.[92-94] Prospective studies in England and Finland have demonstrated that chronic stress is a risk factor for metabolic syndrome, which in turn increases the risk of type 2 diabetes.[95, 96] *Delahanty et al* used data from the DPP study, and found that perceived stress was significantly associated with higher BMI in the DPP cohort, but also that stress, anxiety, binge-eating, craving, and emotional eating were all correlated with one another and with BMI. The complex associations between psychological stress, self-management behavior, and physiological outcomes need further study as financial hardship and food insecurity may influence these associations. Additionally, there is a need for more research to understand the overall role of household food insecurity in diabetes management, and a need for interventions that address the challenges of poverty that are preventing optimal self-care and management of diabetes in this study population.

Limitations

This study had several limitations that should be considered. First, the cross-sectional nature of this study does not allow us to make causal arguments, and the specificity of the population means one cannot generalize these findings to other contexts. Another important drawback is the relatively small sample size of the total study sample urging abundant caution in the interpretation of null findings. The relatively low sample size was reflected on estimates with wide confidence intervals limiting the precision of these estimates. All measures except BMI and HbA1c were self-reported and can be affected by social desirability bias. This may especially be the case for patients who participated in the survey with family or friends within hearing range. While interviewers did the best they could to ensure privacy for the study participant, many times onlookers were invited over by the patient themselves, or the space was too small to exclude other family members from the conversation. Additionally, psychometric analysis for the Morisky Scale (medication adherence) and the Stanford Exercise Behaviors Scale (exercise) did not prove to be robust in this study, so these variables should be interpreted with caution.

Differences in location of the interview and the blood draw could have potentially biased the sample. The research team made an attempt to visit every patient that it was estimated could be reached within an hour long bus-ride from the clinic. A total of 41 (20.3%) patients from the original list of diabetes patients provided to us by the clinic were deemed too far away to contact. If patients came into the clinic during the time of data collection, blood samples for the HbA1c were taken at the clinic and processed immediately. Blood samples of patients who were interviewed at their home were transported back to the clinic after several hours. This procedural difference could also introduce variation in the sample, however, we controlled for this variable in the adjusted models.

Conclusion

This study found that a majority (74.3%) of the Futuro Valdivia clinic's diabetes patients have poor management (HbA1c >7%). Our findings indicate that individuals with severe food insecurity and who use diabetes medications have higher odds of poor management. The high proportion of poorly managed diabetes patients is a signal that better care and support for diabetes patients is needed in this region of Ecuador. The cross sectional nature and small sample size of this study limits the interpretations of our findings. More longitudinal studies with greater power are needed to confirm these results, and to clarify the mechanisms by which poverty in this area may be affecting diabetes management.

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Appendix

Characteristics of the Study Population [a, b, c]

[a] Table values are mean ± SD for continuous variables and n (column %) for categorical variables.

[b] Numbers may not sum to total due to missing data, and percentages may not sum to 100% due to rounding.

[c] P-value is for X^2 or Fisher's exact test for categorical variables and t-test for continuous variables.

Table 1A Demographic Characteristics

Participant Characteristic	All Participants Number (N%)	Mean	SD	Well Managed (Hba1c ≤ 7) N=38 Number (N%)	Poorly Managed (Hba1c >7) N=110 Number (N%)	P-value	
Gender							
Male	61 (41.2)			13 (34.2)	48 (43.6)	0.31	
Female	87 (58.8)			25 (65.8)	62 (56.4)		
Age (years)							
		56.79	13.26	59.5 + 16.3	55.8 + 12.0		0.14
≤50	50 (33.8)			13 (34.2)	37 (33.6)	0.14	
51-65	63 (42.6)			12 (31.6)	51 (46.4)		
>65	35 (23.7)			13 (34.2)	22 (20.0)		
Marital Status							
Married	110 (74.8)			26 (68.4)	84 (76.4)	0.33	
Other	38 (25.7)			12 (31.6)	26 (23.6)		
Number of People in Household							
		5.05	2.31	4.9 + 2.4	5.1 + 2.3		0.68
Education							
Grade school or less	127 (85.8)			37 (97.4)	90 (81.8)	0.02	
Greater than grade school	21 (14.2)			1 (2.6)	20 (18.2)		
Employment Status							
Full-time	36 (24.3)			10 (26.3)	26 (23.6)	0.04	
Part-time	31 (21.0)			2 (5.3)	29 (26.4)		
Not working	61 (41.2)			21 (55.3)	40 (36.4)		
Disabled	20 (13.5)			5 (13.2)	15 (13.6)		
SES (household items)							
High SES	80 (54.1)			16 (42.1)	64 (58.2)	0.09	
Low SES	68 (46.0)			22 (57.9)	46 (41.8)		

TABLE 1B Clinical Characteristics

Participant Characteristic	All Participants Number (N%)	Mean	SD	Well Managed (Hba1c ≤ 7) N=38 Number (N%)	Poorly Managed (Hba1c >7) N=110 Number (N%)	P-value	
Time since Diagnosis							
		7.18	6.9	5.3 + 5.8	7.8 + 7.1		0.06
0-2 years	47 (32.6)			16 (44.4)	31 (28.7)	0.07	
3-5 years	34 (23.6)			10 (27.8)	24 (22.2)		
≥6 years	63 (43.8)			10 (27.8)	53 (49.1)		
Comorbidities							
		1.09	1.1	1.2 + 1.3	1.0 + 1.0		0.34
0	51 (34.7)			14 (36.8)	37 (33.9)	0.34	
1	55 (37.4)			10 (26.3)	45 (41.3)		
2	25 (17.0)			8 (21.1)	17 (15.6)		
3+	16 (10.9)			6 (15.8)	10 (9.2)		
BMI							
		26.13	4.91	26.6 + 4.4	26.0 + 5.1		0.55
<25	51 (44.0)			13 (41.9)	38 (44.7)	0.07	
25-30	49 (42.2)			10 (32.3)	39 (45.9)		
≥30	16 (13.8)			8 (25.8)	8 (9.4)		
Medication Use							
Does not use diabetes meds	32 (21.6)			14 (36.8)	18 (16.4)	0.01	
Uses diabetes meds	116 (78.4)			24 (63.2)	92 (83.6)		
Other Medications							
Takes no other meds	108 (74.5)			23 (62.2)	84 (78.7)	0.05	
Takes other meds	37 (25.7)			14 (37.8)	23 (21.3)		
Medication Adherence							
Good adherence	44 (37.9)			8 (33.3)	36 (39.1)	0.60	
Poor adherence	72 (62.1)			16 (66.7)	56 (60.9)		
Location of Blood Draw							
Clinic	23 (15.5)			10 (26.3)	13 (11.8)	0.03	
Other	125 (84.5)			28 (73.7)	97 (88.2)		
Time Since Diagnosis							
		7.18	6.9	5.3 + 5.8	7.8 + 7.1		0.06
0-2 years	47 (32.6)			16 (44.4)	31 (28.7)	0.07	
3-5 years	34 (23.6)			10 (27.8)	24 (22.2)		

TABLE 1C Behavioral Characteristics

Participant Characteristic	All Participants Number (N%)	Mean	SD	Well Managed (Hba1c ≤ 7) N=38 Number (N%)	Poorly Managed (Hba1c >7) N=110 Number (N%)	P-value	
Main Shopper							
Self	84 (57.1)			21 (55.3)	63 (57.8)	0.79	
Other	63 (42.9)			17 (44.7)	46 (42.2)		
Main Cook							
Self	53 (36.1)			13 (34.2)	40 (36.7)	0.09	
Other	80 (54.4)			18 (47.4)	62 (56.9)		
Shared responsibility	14 (9.5)			7 (18.4)	7 (6.4)		
Snacking Frequency							
Rarely	33 (22.8)			8 (21.1)	25 (23.4)	0.71	
Weekly	42 (29.0)			13 (34.2)	29 (27.1)		
Daily	70 (48.3)			17 (44.7)	53 (49.5)		
Replacing Meals with Snacks (per week)							
		1.62	0.75	1.5 + 0.7	1.6 + 0.7		0.53
0-1 meals	77 (52.7)			22 (57.9)	55 (50.9)	0.81	
2-4 meals	48 (32.9)			11 (29.0)	37 (34.3)		
5+ meals	21 (14.4)			5 (13.2)	16 (14.8)		
Food Insecurity							
Mild food insecurity	87 (62.1)			25 (73.5)	62 (58.5)	0.12	
Severe food insecurity	53 (37.7)			9 (26.5)	44 (41.5)		
Dietary Diversity							
Good	13 (9.0)			2 (5.3)	11 (10.3)	0.24	
Moderate	112 (77.2)			28 (73.7)	85 (78.5)		
Poor	20 (13.8)			8 (21.1)	12 (11.2)		
Exercise (per week)							
Less than 1 hour	25 (17.1)			7 (18.4)	18 (16.7)	0.29	
1-3 hours	24 (16.4)			3 (7.9)	21 (19.4)		
3+ hours	97 (66.4)			28 (73.7)	69 (63.9)		
Payment for Diabetes Medication							
Insurance	28 (24.1)			5 (20.8)	23 (25.0)	0.95	
Out-of-Pocket	64 (55.2)			14 (58.3)	50 (54.4)		
Other	24 (20.7)			5 (20.8)	19 (20.7)		
Mental Health							
No depression	100 (73.5)			24 (72.7)	76 (73.8)	0.90	

Depression	36 (26.5)			9 (27.3)	27 (26.2)		
Social Support							
High social support	68 (48.2)			13 (37.1)	55 (51.9)	0.34	
Moderate social support	65 (46.1)			20 (57.1)	45 (42.5)		
Little/no social support	8 (5.7)			2 (5.7)	6 (5.7)		
Sleep (hours)							
		7.32	1.96	7.8 + 2.0	7.2 + 1.9		0.07
Enough Sleep							
No	57 (38.8)			11 (29.7)	46 (41.8)	0.19	
Yes	90 (61.2)			26 (70.3)	64 (58.2)		
Smoking Status							
Never smoked	103 (69.6)			29 (76.3)	74 (67.3)	0.30	
Ever smoked	45 (30.4)			9 (23.7)	36 (32.7)		
Alcohol Status							
Never drank	40 (27.2)			12 (31.6)	28 (25.7)	0.38	
Drank previously	76 (51.7)			16 (42.1)	60 (55.1)		
Drinks currently	31 (20.1)			10 (26.3)	21 (19.3)		

TABLE 2 Unadjusted associations between study variables and poorly managed diabetes (HBA1C > 7)

	N	% poorly-managed	OR (95% CI)
Gender			
Male	61	78.7	1.00
Female	87	71.3	0.67 (0.31, 1.45)
Age (years)			
<u><</u>50	50	74.0	1.00
51-65	63	81.0	1.50 (0.61, 3.64)
>65	35	62.9	0.60 (0.23, 1.51)
Marital Status			
Married	110	76.4	1.00
Other	37	68.5	0.67 (0.29, 1.51)
Number of People in Household			1.04 (0.88, 1.22)
Education			
Grade school or less	127	70.9	1.00
Greater than grade school	21	95.2	8.22 (1.06, 63.50)
Employment status			
Full-time	36	72.2	1.00
Part-time	31	93.6	5.58 (1.12, 27.84)
Not working	61	65.6	0.73 (0.30, 1.80)
Disabled	20	75.0	1.15, (0.33, 4.02)
SES (household items)			
High SES	80	80.0	1.00
Low SES	68	67.7	0.52 (0.25, 1.10)
Time Since Diagnosis			
0-2 years	47	66.0	1.00
3-5 years	34	70.6	1.24 (0.48, 3.21)
<u>></u>6 years	63	84.1	2.74 (1.11, 6.77)
Comorbidities			
0	51	72.6	1.00
1	55	81.8	1.70 (0.68, 4.28)
2	25	68.0	0.80 (0.28, 2.28)
3+	16	62.5	0.63, (0.19, 2.06)
BMI			
<25	51	74.5	1.00
25-30	49	79.6	0.97 (0.41, 2.30)
<u>></u>30	16	50.0	0.33 (0.11, 0.94)
Medication Use			

Does not use diabetes meds	32	56.3	1.00
Uses diabetes meds	116	79.3	2.98 (1.30, 6.84)
Other Medications			
Takes no other meds	107	78.7	1.00
Takes other meds	37	62.2	0.45 (0.20, 1.00)
Medication Adherence			
Good adherence	44	81.8	1.00
Poor adherence	72	77.8	0.78 (0.30, 2.04)
Location of Blood Draw			
Clinic	23	56.5	1.00
Other	125	77.6	2.67 (1.06, 6.72)
Main Shopper			
Self	84	75.0	1.00
Other	63	73.0	0.90 (0.43, 1.90)
Main Cook			
Self	53	75.5	1.00
Other	80	77.5	1.12 (0.50, 2.53)
Shared responsibility	14	50.0	0.33 (0.10, 1.10)
Snacking Frequency			
rarely	33	76.8	1.00
Weekly	42	69.1	0.71 (0.26, 2.00)
Daily	70	75.7	1.00 (0.38, 2.62)
Replacing Meals with Snacks (per week)			
0-1 meals	96	71.4	1.00
2-4 meals	29	77.1	1.35 (0.58, 3.10)
5+ meals	21	76.2	1.28 (0.42, 3.92)
Food Insecurity			
Mild food insecurity	69	71.3	1.00
Severe food insecurity	71	83.0	1.97 (0.84, 4.63)
Dietary Diversity			
Good	13	84.6	1.00
Moderate	112	75.0	0.55 (0.11, 2.61)
Poor	19	60.0	0.27 (0.05, 1.57)
Exercise (per week)			
Less than 1 hour	27	72.0	1.00
1-3 hours	22	87.5	2.72 (0.61, 12.10)
3+ hours	97	71.1	0.96 (0.36, 2.55)
Payment for Diabetes Medication			

Insurance	28	82.1	1.00
Out-of-Pocket	64	78.1	0.78 (0.25, 2.41)
Other	24	79.2	0.83 (0.21, 3.29)
Mental Health			
No depression	100	76.0	1.00
Depression	36	75.0	0.95 (0.39, 2.29)
Social Support			
High social support	68	80.9	1.00
Moderate social support	65	69.2	0.53 (0.24, 1.19)
Little/no social support	8	75.0	0.71 (0.13, 3.92)
Sleep (hours)			0.84 (0.69, 1.02)
Enough Sleep			
Yes	90	80.7	1.00
No	57	71.1	0.59 (0.26, 1.31)
Smoking Status			
Never smoked	103	71.8	1.00
Ever smoked	45	80.0	1.57 (0.67, 3.66)
Alcohol Status			
Never drank	40	70.0	1.00
Drank previously	76	79.0	1.61 (0.67, 3.85)
Drinks currently	31	67.7	0.90 (0.33, 2.48)

* Numbers may not sum to total due to missing data.

TABLE 3 Fully adjusted and reduced multivariate logistic regression models predicting poor diabetes management (N=105)

Full Model (N=105)		*Reduced Model (N=105)*	
Characteristic	**Adjusted OR (95% CI)**	**Characteristic**	**Adjusted OR (95% CI)**
Gender		**Gender**	
Male	reference	Male	reference
Female	1.42 (0.26, 7.81)	Female	1.21 (0.38, 3.83)
Age		**Age**	
≤50 years	reference	≤50 years	reference
50-65 years	2.23 (0.52, 9.60)	50-65 years	2.68 (0.70, 10.25)
>65 years	0.32 (0.06, 1.73)	>65 years	0.46 (0.11, 1.88)
Education		**Education**	
Grade school or less	reference	Grade school or less	reference
more than Grade school	5.26 (0.46, 61.26)	more than Grade school	7.63 (0.67, 87.12)
SES (household items)		**BMI**	
High SES	reference	<25	reference
Low SES	0.30 (0.08, 1.16)	25-30	0.98 (0.28, 3.49)
Time Since Diagnosis		≥30	0.33 (0.07, 1.52)
0-2 years	reference	**SES (household items)**	
3-5 years	2.26 (0.41, 12.35)	High SES	reference
≥6 years	2.84 (0.58, 13.84)	Low SES	0.30 (0.09, 1.02)
BMI		**Food Insecurity**	
<25	reference	Mild food insecurity	reference
25-30	1.36 (0.28, 6.71)	Severe insecurity	3.45 (1.05, 11.37)
≥30	0.43 (0.07, 2.70)	**Medication Use**	
Medication Use		Does not use diabetes meds	reference
Does not use diabetes meds	reference	Uses diabetes meds	6.02 (1.48, 24.57)
Uses diabetes meds	5.98 (1.15, 31.06)	**Location of Blood Draw**	
Additional Medications		Clinic	reference
Takes no other meds	reference	Other	3.33 (0.88, 12.64)
Takes other meds	0.58 (0.12, 2.69)		

Location of Blood Draw	
Clinic	reference
Other	3.54 (0.79, 15.83)
Main Cook	
Self	reference
Other	1.04 (0.18, 5.98)
Shared responsibility	0.27 (0.04, 2.01)
Food Insecurity	
Mild food insecurity	reference
Severe food insecurity	2.97 (0.79, 11.07)
Enough Sleep	
No	reference
Yes	0.78 (0.17, 3.60)
Hours of Sleep	0.82 (0.55, 1.22)