Global Journal of Medicine & Public Health

Improving diabetes care in Northern Haiti

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ABSTRACT

Aims

We attempted to improve clinical outcome measures (HbA1c, blood pressure, preventive foot care) in a high-risk population of diabetic patients living in Northern Haiti.

Methods

We enrolled patients followed at the Justinian University Hospital's Diabetes Clinic, who qualified by having either a HbA1c > 9% (75 mmol/mol) or blood pressure > 160/95. Culturally-appropriate educational materials were used to instruct patients and providers, and evidence-based algorithms for the management of glycemia, blood pressure and foot care were utilized.

Results

Despite delays due to a serious earthquake, cholera and political unrest, we enrolled a total of 101 patients. Despite high rates of adoption of study protocols, we saw no improvement in HbA1c (pre- 10.8 ± 0.27%, 95 ± 2.9 mmol/mol, vs post- 10.8 ± 0.33%, 95 ± 3.6 mmol/mol), systolic (144 ± 3.3 vs 143 ± 3.7 mmHg) or diastolic (89 ± 1.9 vs 87 ± 1.8 mm Hg) blood pressure. Focus group discussions identified the lack of food and money as the major barriers to patients' self-management of diabetes. There was a common belief that psychological stressors were the cause of diabetes. We found no evidence that traditional healers (dòktè fèy) or spiritual beliefs (vodou) worked in opposition to medical care.

Conclusions

Efforts to translate evidence-based clinical algorithms into improved clinical outcomes may be ineffective in fragile states such as Haiti unless food scarcity and extreme poverty are first addressed.

Keywords: Poverty, Food scarcity, Access to care, Acculturation, Translation

GJMEDPH 2021; Vol. 10, issue 6 | OPEN ACCESS

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Conflict of Interest—none | **Funding—**The research was supported by International Diabetes Federation BRIDGES grant (St09-025)

INTRODUCTION

Haiti has the lowest life expectancy in the Western Hemisphere at 64 years[1], combined with the lowest government expenditure on health care.[2] Extreme poverty, illiteracy, lack of material resources, and political instability all contribute to a high chronic disease burden. Natural disasters, such as the massive earthquake that devastated Haiti in January 2010, and the cholera epidemic that struck later that same year, have placed an extraordinary strain on Haiti's already-fragile public health system.

It is difficult to find data to estimate the burden of diabetes in Haiti. The International Diabetes Federation Diabetes Atlas[3] estimates the prevalence

of diabetes and diabetic complications using data from Jamaica, which may not be applicable to a much poorer country such as Haiti. We have previously reported a prevalence of diabetes in the Port-au-Prince region, of 7.4% in men and 11.1% in women.[4] Hypertension was found in more than two-thirds of men and women aged 40 years and older. In a report on diabetes practice in developing countries, only 7.5% of type 1, and 3.6% of type 2, diabetic patients met recommended targets for control.[5]

In an effort to improve the care of patients living with diabetes in the region surrounding Cap-Haitien, Haiti's second largest city, we developed a collaborative effort between the volunteer organization Konbit Sante, the physician and nursing staff at the Hôpital Universitaire Justinien (HUJ) in Cap-Haitien, and colleagues working at the Fondation Haïtienne de Diabète et de Maladies Cardio-Vasculaires (FHADIMAC) in Port-au-Prince. Based on initial observations and interviews of key informants, a translational research project was undertaken to implement a diabetes intervention by delivering the three most cost-effective interventions used in other developing countries[6]:

1) improved glycemic control in people with poorly managed diabetes (HbA1c above 9%),
2) blood pressure control in those with blood pressure above 160/95, and
3) preventive foot care strategies in people at high risk of ulcers and amputation. We used the RE-AIM framework[7] to analyze key elements of successful translation into this challenging environment.

Selection of subjects

The Hôpital Universitaire Justinien (HUJ) is a 250-bed teaching hospital in Cap-Haïtien operated by the Haitian Ministry of Health. It is the largest health care provider in northern Haiti and serves as the reference hospital for an estimated 825,000 people. The Diabetes Clinic at HUJ is staffed by a full-time registered nurse and Internal Medicine (IM) resident physicians. There are approximately 250 patient visits each month. At the beginning of this project, serum glucose determinations could not usually be made on the day of visit due to limited laboratory services. Patients presented to the clinic in late stages of disease, almost always having run out of their supply of medications long beforehand. Insulin supply was limited to NPH (Neutral Protamine Hagedorn); Regular insulin was often unavailable and for most patients unaffordable even when it was available.

After making several trips to Haiti with Konbit Sante, a Maine-based volunteer partnership dedicated to working with Haitian colleagues to build capacity within Haiti's public health system (MSPP), the Principal Investigator (PI) (JTD) collaborated with colleagues at HUJ and at FHADIMAC to design this translational research project funded by an IDF BRIDGES award. The research protocol had been approved by the Maine Medical Center Institutional Review Board, as well as the HUJ Ethics Committee, Haiti's IRB equivalent. The funding announcement arrived just as a catastrophic 7.0 M_w earthquake struck near Port-au-Prince on January 12, 2010.

The PI traveled to Cap-Haitien in March, 2010, to assess the impact of the earthquake on hospital services, to assess the readiness of hospital staff to initiate the project, and to interview and hire a research Nurse, Nijnie Jasmin, and two community health workers (Agents Santé). Their responsibilities would be to supervise Diabetes Clinic visits, provide group educational sessions on Diabetes Clinic days (Tuesday and Friday mornings), screen and enroll patients into the study after obtaining verbal consent, obtain and record clinical measures including capillary blood glucose (CBG) and HbA1c measurements, arrange for scheduled follow-up visits, and make home visits on at least a monthly basis to consolidate education, identify problems or barriers to care, and facilitate diabetes self-management.

Patients were sequentially enrolled into the study if they met either criterion: blood pressure above 160/95, or HbA1c above 9%. HbA1c measurement was performed if the patient's capillary glucose was greater than 150 mg/dL in the fasting state (patients were uniformly fasting on the morning of clinic visit due to limited food supply).

MATERIALS AND METHODS

In collaboration with senior Internal Medicine residents at HUJ, we developed a clinic flow-sheet ('dossier') for the purpose of tracking clinical measures (CBG, HbA1c, blood pressure, body weight, foot exam findings) and educational session attendance record, as well as current and past medications and dosage adjustments. Prior to this, there was no method for tracking biometrics and information was difficult to locate due to the disorganized hand-written notes on loose sheets of paper. We adapted evidence-based protocols for the adjustment of glucose-lowering medications based on current dosages and the CBG reading at the time of clinic visit,[8] as well as the STITCH-algorithm[9] to adjust doses of generic antihypertensive medications, including ACE inhibitors and thiazide diuretics, in combinations shown to increase efficacy and reduce side effects.[10]

After educating Internal Medicine residents and the research nurse in the performance of a detailed foot exam, individuals were classified according to a modified version of the Diabetic Foot Risk Classification System of the International Working Group on the Diabetic Foot (IWGDF).[11] The findings were used to classify risk category and guide treatment and follow-up.[12] Each of the algorithms was translated into French, and then printed on posters to be displayed on the walls of the Diabetes Clinic.

CBG readings were determined from fingerstick samples using Abbott FreeStyle glucose meters and test strips, donated by the company. HbA1c determinations were made using the Bayer A1CNow® System.[13] Initial problems with error messages due to high ambient temperature in the clinic were solved initially by bringing icepacks in an insulated container, and later by transporting blood samples to an air-conditioned office to perform the measurements.

RESULTS

After initial delays due to the earthquake, and a subsequent cholera outbreak, we enrolled a total of 101 patients between October 2010 and October 2011. Their baseline characteristics are shown in Table 1. Patients came from as far away as Limonade, 8km from Cap-Haitien. The most arduous trip was made by an elderly woman with a below-the-knee amputation, who had to struggle down the hill upon which she lived, take a water taxi, and then wait for a tap-tap (pickup truck used as a bus) to bring her over a rough dirt road to the clinic. Overall, 88% came from the Cap-Haitien metropolitan area within a 5km radius.

Cultural challenges

One of the difficulties in conducting this project was poor communication between Haitian and US-based research team members. Despite Haitian staff being paid by Konbit staff, who helped facilitate communication, the PI had difficulty learning the status of patient enrolment and screening without travelling in person to Haiti. Data quality needed to be carefully reviewed by the PI during quarterly visits. There was no reliable method to ship supplies, such as Bayer A1CNow® kits and glucose test strips, to Haiti other than having travelling volunteers bring them during trips to Haiti. Fortunately, Novo Nordisk had provided a one-year's supply of Novolin N to Haiti following the earthquake, allowing us to transfer insulin from FHADIMAC in Port-au-Prince to Cap-Haitien on a regular basis during the period of study. Research team members were threatened if money was not paid to hospital staff who were not directly involved in the research. One person with type 1 diabetes, who ran a diabetes support group, had been interviewed as a 'positive deviant'[14] (someone who seems to do better than others in the same situation) in order to gain insight into living with diabetes in Haiti, but later denounced our programme and attempted to turn patients away when he was not hired on the grant. Medications and supplies that were provided gratis for the support of enrolled patients were diverted for sale under the pretext that this was necessary to purchase other needed supplies.

Due to the aforementioned logistical challenges, patient enrolment and follow-up were less than anticipated. We were able to obtain follow-up data at 6 months in 64 patients. Ten patients had died and the remainder had either dropped out, moved away, or were hospitalized at the time of follow-up. Table 2 shows the outcome results for the 64 patients in whom we were able to collect follow-up information.

Table 1 Baseline characteristics of enrolled patients (N=101)

	Mean ± SEM (where applicable)	Range
Gender	21 M/80 F	
Age	54 ± 1.2	17 - 80
Diabetes Type 2, n (%)	96 (95)	
Diabetes duration (years)	8.4 ± 0.7	0.25 - 40
Weight (lbs)	134 ± 3.0	80 - 233
BMI	24 ± 0.5	14.5 - 40
Fasting CBG (mg/dl)	268 ± 9.6	105 - 545
HbA1c (%)	10.6 ± 0.23	5.4 † - 13.0
BP Systolic (mm Hg)	145 ± 2.8	90 - 220
BP Diastolic (mm Hg)	91 ± 1.6	60 - 140
IWGDF Classification*		
0	66	
1	12	
2	17	
3 (Amputation)	6	

† *presumed hemoglobinopathy, e.g. sickle cell trait*

** IWGDF classification: 0, no loss of protective sensation (LOPS), peripheral artery disease (PAD), or deformity; 1, LOPS ± deformity; 2, PAD ± LOPS; 3, history of ulcer or amputation*

Table 2 Clinical outcomes after 6 months (n=64)

	Baseline	6 months
Weight (lbs)	134 ± 3.9	137 ± 4.1
Fasting CBG	267 ± 12.1	236 ± 14.2†
HbA1c (%)	10.8 ± 0.27	10.8 ± 0.33
BP systolic	144 ± 3.3	143 ± 3.7
BP diastolic	89 ± 1.9	87 ± 1.8
New amputations	n/a	0

† *$p < 0.05$, paired t-test*

Table 3 Logistic regression analysis with dependent variable = mortality

Parameter	Estimate	Std. Error	Wald Chi-Square	Pr>ChiSq
Intercepts	16.44	38.018	0.187	0.665
HbA1c	-2.85	3.919	0.530	0.467
BP Systolic	-0.131	0.256	0.262	0.609
HbA1c*SBP	0.016	0.026	0.377	0.540
S. Creatinine	3.952	1.968	4.033	0.045

Study effectiveness and challenges

Despite a significantly lower fasting CBG at the 6 months visit compared to the baseline period, there was only a weak correlation (r=0.38) between these values. Once these negative results, in terms of our primary outcomes measures of HbA1c and blood pressure, were apparent, our focus was on collecting long-term follow-up data on as many individuals as possible, rather than on enrolling new patients. Despite this, we were able to obtain 1-year outcome results on only 20 individuals, with findings similar to the 6-months results. Just prior to the end of our two-year period of research funding, the research nurse reported that someone had broken into the HUJ Diabetes Clinic and stolen all the patient dossiers. During periodic review of the dossiers, we determined the extent to which the Internal Medicine residents had followed the clinical algorithms. The blood pressure algorithm was followed in 89% of cases, the glycemic control algorithm in 43%. The number of antihypertensive agents prescribed were 0 (15%), 1 (21%), 2 (30%), 3 (30%) or 4 (6%). Hydrochlorothiazide was prescribed for 65% of cases, and ACE inhibitors for 90% of patients with hypertension. The prior practice of prescribing alpha-methyldopa in a large cohort of individuals was eliminated during the study period. Deviation from the glycemic algorithm was mainly failure to start insulin. Hyperglycemia on the day of clinic visit was typically treated with oral or intravenous hydration with resolution; 59% of patients were treated with metformin, 33% with insulin, 56% with a statin and 84% with aspirin.

To explore the reasons for lack of improvement in clinical outcomes, despite adoption of prescribing protocols, the Agents Santé designed a brief survey to administer during home visits. When asked which of their antihypertensive and diabetes oral agents had patients taken on the day prior to the visit, 71% stated they had taken all their medications, but this response varied from 88% in those treated with a single drug to 29% in those treated with four pills. The most common reason given for not taking medications were lack of money to purchase food and medications. Patients did not take their medications if they could not eat. Patients enrolled in the study assumed that all medications would be provided to them free of charge and would not purchase them.

Logistic regression: mortality, previous amputation

Due to the high mortality (6 patients) over the 6-month period of follow-up, we performed logistic regression analysis in order to determine which baseline characteristics were most strongly predictive of mortality (Table 3). Although several independent variables, including systolic and diastolic blood pressure, HbA1c and male sex, were significantly predictive of mortality in univariate analyses, in multivariate analyses only serum creatinine was a significant predictor of mortality, with an odds ratio of 52.0 for each 1 mg/dL increase in value. Relatively few (n=7) patients had serum creatinine values above 1.5, and the highest value was 2.4 mg/dL. The inverse relationship of HbA1c to mortality can be explained by our recruitment criteria, in that some individuals with normal blood pressure qualified for enrolment due to elevated blood glucose, and for others the reverse was true. Systolic and diastolic blood pressure were strong predictors of mortality in univariate analyses. We also evaluated baseline characteristics associated with previous amputation: only the duration of diabetes showed a significant relationship, with an odds ratio of 1.16 ($p < 0.026$) for each additional year of duration.

DISCUSSION

This translational research project was beset with many challenges, including a natural disaster, epidemic disease, political instability and cultural barriers that made it very challenging to improve medical care in northern Haiti. In terms of our translational framework (RE-AIM),[7] we were successful in reaching a broad sample of high-risk patients, despite transportation difficulties. Word spread quickly that a new diabetes project was underway, leading so many patients to transfer their care to the HUJ Diabetes Clinic that it was hard to accommodate the increased demand. Clinic hours were expanded and increased physician hours were dedicated, but it is possible that patients not meeting our enrolment criteria had decreased access to the clinic. We attribute the high rate of adoption of clinical algorithms to the strong support of leaders in the Internal Medicine department (MP). Failure to institute insulin treatment as suggested by our glycemic algorithm likely reflects the problems of initiating and maintaining this form of therapy in Haiti, and suggests that a protocol adapted from a US-

based, nurse practitioner-led intervention[8] may not be appropriate for the majority of patients. The high level of commitment shown by our research nurse, two Agents Santé, and senior medical residents did not translate into the hoped-for effectiveness of the intervention to improve our chief outcome measures. This demonstrates the limits of translational research, which does not take into full account the many barriers to care (poverty, food insecurity) faced by this patient population. We questioned whether a reliance on traditional healers (doktè fè) or other normative beliefs outside of a Western medical approach might be a contributory factor, but found no evidence to support this during home visits or interviews. The final component of the RE-AIM framework – maintenance – is uncertain. We developed clinical protocols, educated Internal Medicine residents, and created clinical tools to track patient outcomes which remain intact, but we think their regular use will be less now that the period of research funding has ended. The Agents Santé have already moved on to another project, resulting in loss of a valuable educational asset. There is no guarantee that our well-trained and highly-skilled research nurse will find a position in Haiti's public health system.

The most important aspect of this research may be not merely the demonstration of how challenging it is to conduct translational research in Haiti, but in providing longitudinal data in a high-risk subset of patients with diabetes. The baseline prevalence of lower-extremity amputation is higher than previously estimated[3] and our mortality data are striking and sobering. The important role of even mild degrees of chronic kidney disease in shortening life expectancy is not surprising, given the prevalence of hypertension and challenges in achieving blood pressure control. These results provide additional support to the emphasis that WHO has placed on the control of non-communicable diseases in developing countries.[15]

ACKNOWLEDGEMENT

This research was supported by an International Diabetes Federation BRIDGES grant, *Improving Diabetes Care in Cap Haitien, Haiti* (ST09-025), with quarterly feedback from Ronan L'Heveder and Dr. J.J. Gagliardino. We would also like to acknowledge the support of administrative and technical staff at Konbit Sante Health Partnership, Maine Medical Research Institute, and Fondation Haïtienne de Diabète et de Maladies Cardio-Vasculaires (FHADIMAC).

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