Author's response to reviews

Title: Metabolic control in a nationally representative diabetic elderly sample in Costa Rica: patients at community health centers vs. patients at other health care settings.

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Metabolic control in a nationally representative diabetic elderly sample in Costa Rica: patients at community health centers vs. patients at other health care settings.

Reviewer # 1: Martin Gulliford

Reviewer's remarks:
Metabolic control in a nationally representative elderly sample in Costa Rica

1. Include ‘diabetes’ in the title.

   Done. The title is now: “Metabolic control in a nationally representative diabetic elderly sample in Costa Rica: patients at community health centers vs. patients at other health care settings”.

2. In the Introduction it would help to understand the demographic context by describing the ethnic origins of the study population.

   Done. This paragraph was included in page 4:

   Studying the burden of chronic diseases in Costa Rica is also becoming important because of its demographic context. The population is aging at a rapid pace. The population age 60 and over will triple from 2000 to 2025, and its share among the total population will increase from 8% to 16%. Costa Rica is also one of the Latin American countries with the highest proportion of the elderly living in rural areas (37%). From a racial perspective, most Costa Rican elderly can be classified as of “mixed race”, descendants of a combination of racial backgrounds: Europeans, indigenous groups, African blacks, and Chinese immigrants. However, Costa Ricans see themselves as “white” or “mestizo”. Around 1% of the people age 60 and above classifies themselves as indigenous and less than 2% as blacks, and these minorities are disproportionately located in the province of Limon, in the Caribbean coast. An important proportion of the black community in Costa Rica descends from immigrants who came to work on the railroad from Jamaica and Barbados during the late part of the 19th century. From a demographic perspective, country of origin is more relevant than race, given that 8% of the elderly population was born abroad, especially in Nicaragua [9].
3. In the text, where it refers to ‘risky levels’ this may be an inappropriate term since these are risk factors that are associated with graded elevations in risk.

   Done. Sometimes we used the phrase “poor metabolic control” and sometimes the phrase “elevated levels”, instead of risky levels. These two phrases are used in several articles in the references.

4. In Table 3, to describe the data standard deviations should be given for continuous variables.

   Done.

5. In Tables 4 and 5, it would be worth associating risk factor levels with patterns of treatment. For example, if hypertensive were subjects treated? if treated was their blood pressure controlled? What patterns of therapy were associated with HbA1c and lipids?

   Done. Tables 4 and 5 have several lines with the following subpopulations:

   For HbA1C:
   - People with insulin (n=154)
   - People with oral medication (n=346)

   For SBP, DBP, and blood pressure:
   - People with antihypertensive medication (n=358)

   For triglycerides, and LDL:
   - People with statin medication (n=126)

   Analyzing this by subsamples diminishes statistical power, but produces interesting results. There are differences in glycemic control among people with insulin.

   Besides, all logistic regressions control for use of insulin, and use of oral medication for DM.

6.a. I agree with the authors that the values for metabolic parameters seem surprisingly favourable. Is it possible to evaluate the validity of self-reported diagnoses from the metabolic data? Can we be sure the subjects were diabetic?

   The reviewer’s remark is very important because we know that relying only on self-reported information can produce serious biases. We decided to evaluate the validity of self-reported diabetes using information about prescribed medication, which comes from inspection of “medicine-cabinets” during household visits.
We consider that it is not advisable to evaluate the validity of self-reported diagnoses from metabolic data because metabolic data constitute the dependent variables, so any correction to improve the validity with biomarkers will bias upwards the levels of poor metabolic control. The following paragraph was included in the Discussion (pages 24-25):

An important one is that the study relies on self-reported information which might be affected by reporting bias. Diabetic respondents in the survey were determined based on self-reported answers to the question “Has a doctor or medical personnel ever told you that you have diabetes or high blood sugar levels?” This approach might overestimate the size of the actual diabetic population, and introduce biases in summarizing the outcome variables. If a physician ever told a person that she had impaired glucose tolerance or a one-time elevation in glucose, it is possible that this non-diabetic person will answer “yes” to the question in the survey instrument. We consider that it is inconvenient to validate the self-reported diagnosis with metabolic data because metabolic data is the outcome of this article. Therefore, any correction based on the biomarkers will bias upwards the prevalence of poor metabolic control. A way to explore the bias due to self-report is by using complementary information. The survey inquires about insulin use and other prescribed medication that respondents have in their house. Interviewers ask to see all prescribed drugs and enumerate them. Thirteen percent of the sample (weighted estimate) report not to be taking insulin or oral medication and also lack diabetes-related medication in their houses. If excluding this group, results are roughly the same although the mean levels of the biomarkers and the prevalence of poor metabolic control are slightly higher than with the original sample, but the differences are not statistically significant (α=0.10). The most important differences between the two sets of results are that the difference in prevalence of LDL≥100 mg/dl between community health center patients and patients at other health centers widens, especially among patients with statin medication, and that the percentage of elderly diabetic people without physician examination during the last 12 months drops from 10% to 4%. We decided not to exclude respondents without DM medication from the analyses because, even though some of them might be persons that do not have the disease, others might be diabetic patients that do not care about the treatment for their illness. Therefore, the analysis would be based on a selected population of people that do care about controlling their disease. We do not report the results based on this subsample that excludes these potential non-diabetic respondents, but we can provide them upon request.
6.b. How were metabolic parameters associated with diabetes duration?

Done. Diabetes duration was only associated with glycemic control (HbA1c levels) and with physician examination during the last 12 months. We included the following paragraph in page 17, in the Results section:

Another conclusion drawn from the multivariate models (results not shown in the tables) is that DM duration is associated only with elevated levels of HbA1c and lack of physician examination during the last 12 months. People who were diagnosed more than 4 years ago are twice as likely to have HbA1c ≥ 7% as people with more recent diagnosis. On the other hand, patients with more recent diagnosis are also more likely to lack a DM-related physician examination during the last 12 months. Whether this latter finding is due to the problem of waiting lists in the public health care system is not clear.

Reviewer #2: Martin Gulliford

Reviewer's remarks:

Specific Comments

Most importantly, the authors use the ADA standards for glycemic control as their metric for achieving physiologic targets. It is increasingly widely accepted that ADA goals are very aggressive, not relevant for some patients, and even potentially harmful. For example, a HbA1c of < 7% is probably unattainable in an elderly patient with diabetes who have an A1c of 7.4% and will have very little if any impact on that patient’s risk for adverse outcomes. Using these very strict guidelines can be dangerous because it may lead to over-use of medications (something health systems and patients in places like Costa Rica can ill afford) and will likely lead to increases in hypoglycemic reactions. The authors should review studies by Rodney Hayward, Sandeep Vijan, and others. Two of these are being sent along with this review. In light of these reports, the authors should consider examining the prevalence of patients who meet a more clinically meaningful cutoff for A1c (e.g., >9%), or even better, using different cutoffs based on patients’ age.

We thank the reviewer very much for his comment. We read the papers he sent, as well as some other that we found. We included these papers in the references. We studied the possibility of assigning different cutoff points for different respondents according to an assessment of their disease severity. However, we do not have a full account of respondents’ clinical record, and establishing our own algorithm for classifying respondents by disease severity might raise more doubts than solutions. So, we decided to
present prevalence of poor metabolic control using different cutoff points, and classified by age. This is the new Table 3. We also ran the logistic regression models using different cutoff points, but conclusions did not change, even though the size of the odds ratios did change. Besides, all the logistic regressions control for age, type of diabetes medication (insulin or oral medication), and cardiovascular comorbidities (history of heart attack or stroke). The following two paragraphs were included:

Variation in the standards for HbA\textsubscript{1C}

Given that the target population in this analysis is comprised of elderly Costa Ricans with DM, it is important to acknowledge that ADA standards might be too strict or aggressive as clinical goals, that higher levels of HbA\textsubscript{1C} and blood pressure might not be harmful and might even be beneficial for elderly diabetic patients, and that reduction in these biomarker levels might be more important in improving a patient’s health than just the absolute target [20-24]. Raising the cutoff points diminishes the prevalence of poor control considerably (Table 4). If HbA1C≥9% defines poor glycemic control, instead of HbA1C≥7%, prevalence of poor glycemic control decreases in more than half (15% vs 37%). Similar reductions are observed if elevated SBP is defined as SBP≥150 mmHg instead of SBP≥130 mmHg (42% vs. 78%), and if DBP is defined as DBP≥90 mmHg instead of DBP≥80 mmHg (33% vs. 66%). The proportion of diabetic elderly with elevated HbA\textsubscript{1C} and DBP levels is significantly lower (p<0.05) among people age 75 or more than among people ages 60 to 74. These figures match with previous conclusions that most diabetic elderly in Costa Rica have adequate glycemic control, but are very likely to have high blood pressure levels. Multivariate models in the next section are also estimated using these different cutoff points, but results are not presented in tables unless the conclusions are different from analyses using ADA standards.

We do not present analyses with different endpoints for lipid control because the ADA standards are also recommended by the National Cholesterol Education Program Adult Treatment Panel III [25], given that older persons with DM are considered at high risk of cardiovascular disease. Therefore, ADA standards are not considered as too aggressive. (pages 14-15)

Given the concern posed above about how ADA standards might be too burdensome or strict as clinical goals for diabetic older patients, the logistic models of this section are also estimated using the different cutoff points shown in Table 3 for HbA1C, SBP, and DBP. Compared to the original models with ADA standards, the size of the odds ratios
change, but the same conclusions are drawn: there are no differences in the prevalence of poor levels of HbA1C, SBP, and DBP across health care settings (results are not presented but can be provided upon request). (pages 18-19)

As a more minimalist revision, the authors should make the point in their discussion that 7% A1c is not necessarily a goal for all patients and that many of the 37% of patients in Costa Rica with an A1c > 7% may actually be at an appropriate clinical level. Similar comments could be made about ADA standards for blood pressure and lipids, although the issue is perhaps most important with respect to aggressive control of glycemia.

Done. The following paragraphs were included in the Discussion section, based on the results using different cutoff points (page 19).

If less strict endpoints of HbA1C are used (8% or 9% instead of 7%), the proportion of diabetic older patients with poor glycemic control decreases considerably, and this change strengthens the argument that, among Costa Rican elderly, levels of metabolic control seem favorable.

High prevalence of elevated blood pressure persists even if cutoffs for defining elevated SBP and DBP are raised to 150 mmHg and 90 mmHg respectively.

A somewhat smaller issue is that the question used to identify patients with diabetes “Has a doctor or medical personnel ever told you that you have diabetes or high blood sugar levels,” is sensitive but not specific, in that patients without diabetes but with impaired glucose tolerance or even a 1-time elevation in glucose could be captured in the sample. As such, average A1c may be biased downward from what they would be in a sample that used a more rigorous definition of diabetes.

Done. As answered in the other reviewer’s question 6.a., we tried to evaluate the validity of self-reported diagnosis using information about prescribed medication. Please read answer to point 6.a.

The authors note that all patients have health insurance, but it would be very useful to have some more detail about that coverage. Do patients pay co-payments? What for? Do they pay copays for diabetes-related medications? Is coverage the same in community and other health care settings? How might differences in insurance coverage affect patients’ diabetes care and outcomes?
Although Costa Rica has a mixed health care system, most of the services are provided through a network of hospitals and clinics managed by a public institution—the Social Security system. This system is in part responsible for the high life expectancy levels of Costa Rica [12-13]. The Social Security system is funded from deductions from the payroll, and contributions by the employers and the Government. This is the so-called “contribution regime”. Workers that contribute to the System are entitled to health insurance that allows them and their family to receive free health care services and free medications at any hospital, clinic or community health center run by the Social Security system. Additionally, after a “means test”, the Government provides health insurance to poor people who are not entitled to it through the “contribution regime”. This is the so-called “insurance by the State” or the “non-contribution” regime. Data from the CRELES sample show that the contribution regime covers to 79%; the non-contribution, 15%; and 5% are not insured. There are no copayments for receiving health care. Finally, there are also private hospitals, clinics, and physician offices. People who seek services at these private health care settings have to pay out-of-pocket not only for health care but also for medication and laboratory tests. A new market of private health insurance that caters to high income families is starting to grow in Costa Rica. Interestingly, there are people who use both sectors (e.g., people go for outpatient visits at public clinics but pay out-of-pocket for laboratory examination at private laboratories) [14]. It is important to say also that most of the private hospitals and clinics are located in the Metropolitan Area, where the capital is, while community health centers, and public clinics and hospitals are spread over the Costa Rican territory.

In a similar way, it would be useful to have some information (even if it is somewhat anecdotal) about the processes of care in each sector and how those might contribute to patients’ physiologic health. For example, how many visits do patients have annual in clinics? Are there care management programs? Diabetes education? Are services similar across sectors?
The opening of EBAIS allowed the Government to reorganize the structure of the public health care system. The community health centers are a key component in improving access to primary health care services, since they were first established to serve patients living in rural areas or in poor neighborhoods [13-14]. These community health centers provide outpatient services (preventive services and health promotion), while clinics and hospitals provide primary, secondary and tertiary health care, although they are specialized on the last two types of care: inpatient and more specialized outpatient health care (like surgeries, cancer treatment, intensive care units, or emergencies). Community health centers seek to rationalize resource allocation by referring only those patients who need specialized treatment to specialists in clinics and hospitals. In this sense, they serve as “gate-keepers” for the whole public system. In the past, outpatient visits for chronic disease control were held only in clinics and hospitals. Nowadays, EBAIS have also assumed this kind of consultations as part of their mission of delivering preventive services [14].

Private health care providers deliver the same health care services as the public system, although there is no integration among providers of primary, secondary, and tertiary health care. Besides, private health care services are not organized into health care management programs. Diabetes education and community preventive programs are rare in the private sector, and this is a major difference between both types of providers. The other major difference is the existence of waiting lists in the public system. While patients at public clinical settings have to wait as much as several months (or even years) for an appointment (especially if the appointment is aimed for routine check-ups or laboratory exams), services at private settings are more timely and readily available [14]. Still, a Costa Rican who receives health services at public health centers has gone on average 5.4 times per year to outpatient services, but Costa Ricans that receive services at the private sector have gone on average 3.8 times per year to outpatient visits. The difference is greater among people who have been hospitalized. Among them, the average number of days stayed at a public hospital is 12.6 days and, at a private hospital, it is 5.6 days [15]. In general, access and coverage in the private sector can not be compared to access and coverage in the public sector, since the services of the latter are basically free to all affiliates but affected by long waiting lists, while access and coverage in the private sector depend entirely on purchasing power.
To what do the authors attribute the impressive glycemic control of patients? What lessons are there in Costa Rica’s successes that could help other countries in Latin America?

Done. The following paragraphs were included in the Discussion (pages 20-21).

Why are metabolic control levels so favorable among this population? One possible explanation is that Costa Ricans are commonly inclined to preventive health behaviors. Palmer [37] documents that Costa Rica was, in 1914, one of the few Latin American countries in which the goals of the Rockefeller Foundation anti-hookworm campaign were achieved. According to Palmer, the success of this campaign can be explained by the active involvement of Government employees and rural teachers, and the willingness of the Costa Rican population to trust in these public workers. Regarding more recent data, with a non-representative sample of diabetic patients in San Jose, Costa Rica’s capital, Firestone et al. found that the levels of DM-specific knowledge were greater than in a sample of Spanish-speaking U.S. Latinos in Starr County, Texas [38].

However, in general, achievements in health status in Costa Rica have been linked to effective primary health care services, provided mainly by public institutions and with a strong commitment with equity [12-14]. Although the Costa Rican government had a long tradition of providing those services (which was in part possible because of the non-existence of military expenditures since the 1949 Constitution abolished the armed forces), in the 1970s there was a breakthrough with the opening of hundreds of Rural Health Posts [4]. More recently, a health sector reform launched in 1995 fostered the opening of community health centers or EBAIS to improve the access to primary health care services in underserved areas. It is hard to tell whether this “Costa Rican model” can be exported to other Latin American countries with much larger or less integrated populations, weaker institutions and fewer resources available for public health.

p. 12, first paragraph: The authors refer to “physician control” I know this is a common term in Spanish, but most English speakers will be less confused by “physician visits” (if that is what is meant here).

Done. We change the phrase “physician control” for “physician examination”. We did not use the phrase “physician visit” because the question in the questionnaire asks specifically about When was the last time the respondent was examined by a doctor because of his/her diabetes.