



CLINICAL PROFILE OF PATIENTS BEFORE AND AFTER A DIABETES REVERSAL PROGRAM IN ECUADOR

PERFIL CLÍNICO DE PACIENTES ANTES Y DESPUÉS DE UN PROGRAMA DE REVERSIÓN DE DIABETES EN ECUADOR

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ABSTRACT

Introduction: Chronic non-communicable diseases (NCDs) are the main cause of death in Ecuador and the world, and within them diabetes mellitus is one of the fastest growing morbidity and mortality. **Objective:** To determine if there are differences between the clinical characteristics before and after a diabetes reversal program in Ecuador. **Methods:** Comparative study before and after in the same individual. Patients who voluntarily entered an outpatient clinical program based on Lifestyle Medicine were followed for 8 weeks, measures were taken at the beginning and at the end of this period, which included plant-based nutrition, physical exercise and psychological support. **Results:** Eight patients were analyzed between 40 and 74 years (3 women and 5 men) The comparative analysis before and after the intervention showed significant differences for: Weight ($p = 0.007$), BMI ($p: 0.004$), Glucose ($p = 0, 04$), glycosylated hemoglobin ($p = 0.007$), triglycerides ($p = 0.04$), urea ($p = 0.004$), and TGP ($p = 0.023$). **Conclusions:** There is an improvement in the variables measured after having carried out the "Lifestyle Medicine" reversal program compared to the initial measurements.

Keywords: Life Style, Health Behavior, Health (Source: MeSH NLM).

RESUMEN

Introducción: Las enfermedades crónicas no transmisibles (ECNT) son la principal causa de muerte en Ecuador y el mundo, y dentro de ellas la diabetes mellitus es una de las de mayor crecimiento en morbilidad y mortalidad. **Objetivo:** Determinar si existen diferencias entre las características clínicas antes y después de un programa de reversión de diabetes en Ecuador. **Métodos:** Estudio comparativo antes y después en el mismo individuo. Se realizó el seguimiento de pacientes que ingresaron voluntariamente a un programa clínico ambulatorio basado en Medicina del Estilo de Vida durante 8 semanas, se tomaron medidas al iniciar y al terminar este período, que contempló alimentación basada en plantas, ejercicio físico y apoyo psicológico. **Resultados:** Ocho pacientes fueron analizados entre 40 y 74 años (3 mujeres y 5 hombres) El análisis comparativo antes y después de la intervención mostraron diferencias significativas para: Peso ($p= 0,007$), IMC ($p:0,004$), Glucosa ($p=0,04$), Hemoglobina glicosilada ($p=0,007$), triglicéridos ($p=0,04$), urea ($p=0,004$), y TGP ($p=0,023$). **Conclusiones:** Existe una mejoría en algunas variables medidas después de haber llevado el programa de reversión "Medicina de estilo de vida" en comparación con las medidas iniciales.

Palabras Clave: Estilo de Vida, Conductas Relacionadas con la Salud, Salud (Fuente: DeCS BIREME).

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INTRODUCTION

Chronic noncommunicable diseases are the leading cause of death and disease in the world⁽¹⁾. In Ecuador the situation is no different, according to the results of the STEPS survey on noncommunicable diseases and risk factors, conducted in 2018 to people between 18 and 69 years old, it was obtained that the percentage of people with overweight and obesity is 63.6% (95% CI: 61.8 - 65.4), of these the percentage of people with obesity reaches 25.7% (95% CI: 24.1 - 27.3), with respect to diabetes mellitus, the percentage of people with impaired fasting blood glucose (between 110 and 126

mg/dl) is 7.8% (95% CI: 6.8 - 8.9), of these the percentage of people with elevated fasting blood glucose (greater than 126 mg/dl) reaches 7.1% (95% CI: 6.1 - 8.1)⁽²⁾.

Diabetes mellitus was the second leading cause of death in Ecuador in 2019, being directly responsible for 4,890 deaths⁽³⁾. The participation of this pathology in deaths in Ecuador has grown steadily and considerably in recent years (Figure 1), and may contain a significant underreporting since it is not always identified as the underlying cause of death, so the figure could be even higher.

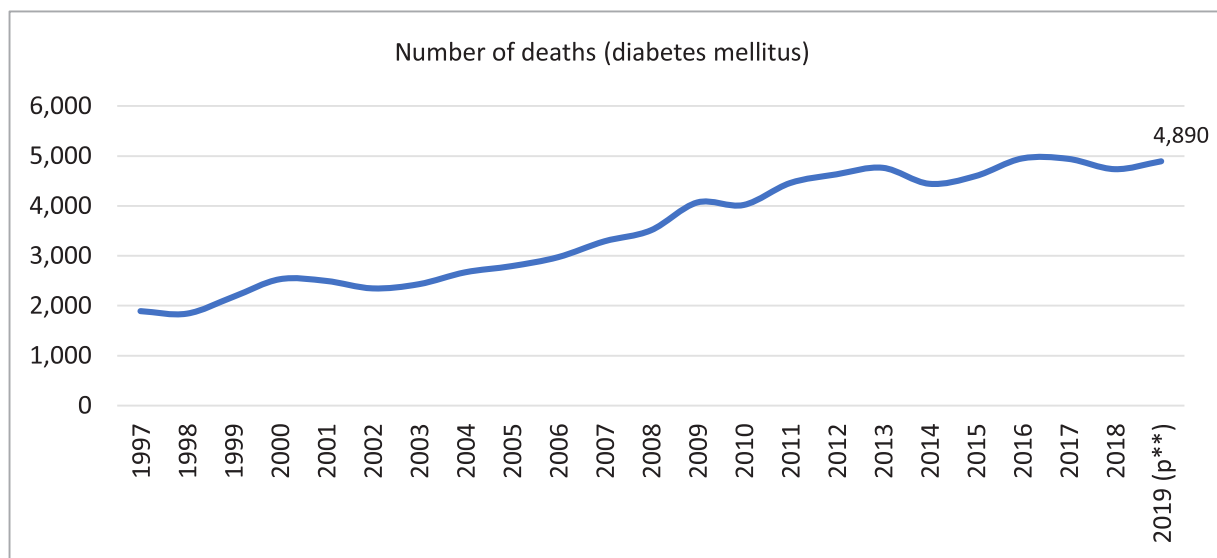


Figure 1. Number of deaths due to Diabetes Mellitus

There are abundant references worldwide that show that lifestyle medicine is effective in improving blood glucose levels in chronic patients with diabetes mellitus, often leading to the reversal of prediabetes or diabetes (4-6). Currently in Ecuador there is not much offer of reversal programs for chronic noncommunicable diseases, being the plan de Medicina de Estilo de Vida (MEV) of Dr. Marco Albuja, the pioneer reversal program of this type in the country,

which consists of eight weeks of transition to a new lifestyle that includes plant-based diet, physical exercise, psychological support and constant clinical monitoring, and a subsequent monitoring of health conditions for at least one year.

Therefore, the objective of the present study is to determine if there are differences between the clinical characteristics before and after a diabetes reversal program in Ecuador.



METHODS

Design and study area

Longitudinal, comparative study of outpatient intervention in Lifestyle Medicine, carried out in Quito - Ecuador, parameters were evaluated before and after the intervention.

Population and sample

The reference population was the patients who voluntarily entered the Lifestyle Medicine program at the Medical Center in Quito, Ecuador. The study consisted of comparing 8 patients (sample size, $n = 8$) who entered the "Lifestyle Medicine" reversal program on different dates. The selection of individuals for the study was done by convenience sampling. This indicates that this study does not seek to extrapolate its results to the general population but seeks to describe the results for this particular set of 8 selected patients⁽⁷⁾.

Variables and instruments

Laboratory samples were taken at baseline and at the end of the program, and the following indicators were measured: Weight (in kilograms), Body Mass Index, basal glucose (mg/dl), basal hemoglobin (mg/dl), basal glycosylated (mg/dl), uric acid (mg/dl), quantitative microalbuminuria (mg/dl), cholesterol (mg/dl), HDL (mg/dl), LDL (mg/dl), triglycerides (mg/dl), TSH (mU/L), creatinine (mg/dl), urea (mg/dl), TGO (mg/dl) and TGP (mg/dl).

Procedures

All 8 patients underwent the outpatient lifestyle medicine intervention consisting of an 8-week program of the stop-and-reverse plan for chronic disease, which included a comprehensive approach of plant-based nutrition, scheduled physical activity, psychological and spiritual support. The program was administered by a team of physicians, nutritionists, psychologists and a physical trainer.

Patients who are candidates for the MEV program undergo an initial consultation where they are given a general explanation of what the program consists of. If

they decide to enter the program, initial examinations are scheduled, which include imaging and blood tests and an initial evaluation in five specialties: nutrition, psychology, cardiology, endocrinology and sports medicine. The eight weeks of the reversal program begin with an inauguration event where operational information is given about the follow-up of the process, which is done in person and in groups using Whatsapp, in which patients must report all food consumed and exercise performed, which is followed and individually fed back by the nutritionist and physical trainer. On a weekly basis, the entire medical and follow-up team evaluates the evolution of each patient in the group, and in these team meetings clinical decisions are made, such as reduction or increase of medications, diet and intensity of physical exercise, among others.

At the end of the 8 weeks, the same series of laboratory tests that were done at the beginning of the program are performed again to evaluate the results in each of the selected patients. The first phase of the program ends with a closing session where the results are shown to all patients and the subsequent follow-up of health conditions is coordinated and monitored if the transition to the new lifestyle is maintained over time.

The COVID-19 pandemic implied certain operational modifications in the MEV program process, since it became impossible to hold the meetings for physical exercise outdoors, the start and end meetings were virtual, but although it is true that technology was used to continue with the program, the conceptual essence of the program did not suffer important modifications.

The 8 patients selected in this study do not belong to a single group of patients, but to several groups over time in order to better capture the variability between various groups of patients and avoid selection bias of a single group with particular conditions, some patients were in groups before the pandemic, and others in groups during the pandemic, which has not yet ended in Ecuador and the world (at the date of publication of this article).

Statistical analysis

To compare the results before and after the program, parametric (paired t-test or for related samples) and nonparametric (Wilcoxon test for paired or related samples) statistical tests were used because of the sample size. All hypothesis tests were performed at a significance level of 5% and tests were performed to assess normality (Shapiro-Wilks test). In the absence of sufficient evidence of normality of the data, the Wilcoxon test was chosen.

Ethical issues

All patients signed an informed consent at admission to participate in the lifestyle medicine program. Institutional approval for the present research work was

obtained, taking into account the ethical principles of clinical research.

RESULTS

The final sample of the study was 8 patients, Table 1 describes the characteristics of weight and biochemical tests taken before and after the program, variations are observed in all variables, such as decrease in weight (from 86.3 kg to 77.2 kg), decrease in glucose (from 143,3 mg/dL to 102.28 mg/dL), in the case of lipids we found a decrease in cholesterol (from 209.9 mg/dL to 186.8 mg/dL) and LDL (from 134.1 mg/dL to 113.5 mg/dL), increase in HDL (from 43.6 mg/dL to 47.5 mg/dL), a decrease in transaminases, as well as creatinine and urea.

Table 1. General characteristics before and after the intervention in the lifestyles of the population studied.

Variable	Before the intervention				After the intervention			
	Minimum	Median	Medium	Maximum	Minimum	Median	Medium	Maximum
Weight	48	85,7	86,3	134	45	78,5	77,2	114
IMC	22,5	31,7	32	42,2	21,1	28,0	28,6	35,5
Glucose	96	124,9	143,6	285	81,7	102,3	102,2	138
HBAIC	5,5	6,6	7,6	12,0	4,7	5,4	5,7	7,9
Uric acid	3,4	6,5	6,22	7,9	4,8	5,5	6,2	9,8
Microalbuminuria	3	6,4	65,7	417	3,0	4,9	63,7	449
Cholesterol	170	191	209,9	266	138,2	191,5	186,8	241
HDL	30,6	42,5	43,6	57	33,5	46	47,4	69,3
LDL	107	129,9	134,1	169	85,8	113,8	113,5	158
Triglyceride	94	130,5	144,1	246	58,5	100	108,3	162
TSH	0,7	1,7	2,6	6,8	1,21	1,87	2,9	9,6
Creatinine	0,6	0,9	0,9	1,6	0,5	0,835	0,8	1,05
Urea	28	34,5	38,0	66,4	15,7	20,85	22,2	32,9
TGO	18	26	29,5	47	16,1	25,4	25,3	36
TGP	20	31	42,3	84,4	13,6	22,9	24,5	37,2

In tabla 2 we found that the variable glucose, uric acid, microalbuminuria, TSH and urea do not follow a normal distribution unlike the other variables.

Table 2. Normality tests

Variable	p-value for Shapiro-Wilks test (Before)	p-value Shapiro-Wilks test (After)
Weight	0,651	0,544
IMC	0,604	0,897
Glucose	0,006*	0,317
HBAIC	0,144	0,090
Uric acid	0,091	0,029*
Microalbuminuria	<0,001*	<0,001*
Cholesterol	0,081	0,894
HDL	0,795	0,654
LDL	0,577	0,378
Triglyceride	0,172	0,299
TSH	0,0123*	0,001*
Creatinine	0,239	0,616
Urea	0,007*	0,424
TGO	0,256	0,915
TGP	0,221	0,343

*p<0,05

Tabla 3 shows the p-values according to the statistical tests performed to compare the values of the variables measured before and after the intervention program.

Table 3. P-values of statistical tests

Variable	p-value of one-tailed t-test	One-tailed Wilcoxon test p-value
Weight	0,001*	0,007*
IMC	<0,001*	0,003*
Glucose	0,050	0,039*
HBAIC	0,028*	0,007*
Uric acid	0,51	0,578
Microalbuminuria	0,831	0,710
Cholesterol	0,101	0,125
HDL	0,151	0,191
LDL	0,085	0,074
Triglyceride	0,039*	0,039*
TSH	0,648	0,578
Creatinine	0,187	0,444
Urea	0,003*	0,003*
TGO	0,150	0,148
TGP	0,022*	0,023*

* p<0,05



DISCUSSION

The results show that the reversal program "Lifestyle Medicine" significantly improves in 8 weeks the indicators related to the pathology of diabetes mellitus in the 8 patients analyzed, such as weight and glucose in which a significant reduction in the level of the variable is observed, and others in which the reduction is less; A similar result was found in a longitudinal study conducted in women, where a significant improvement in anthropometric measures (weight, BMI, body fat, lean mass) was obtained, but no comprehensive intervention was performed on the participants, so no metabolic data were collected, where similar results to our study could possibly be found⁽⁸⁾.

Likewise, most of the variables follow a normal distribution, with the exception of glucose, uric acid, microalbuminuria, TSH and urea. After performing normality tests, it is concluded that the following variables improved significantly after the "Lifestyle Medicine" reversal program: Weight, BMI, glucose, glycosylated hemoglobin, triglycerides, urea and TGP, this means that the implementation of lifestyle change programs are adequate to reduce the morbimortality of non-communicable diseases, such as diabetes mellitus, as well as to decrease its incidence, in addition these programs must have an adequate support team for the integral follow-up of the person, as pointed out in a longitudinal study conducted in adolescents with overweight or obesity, although they did not find significant results in all metabolic variables, such as cholesterol and uric acid levels, good results were obtained in the anthropometric variables⁽⁹⁾, as well as in a review study⁽¹⁰⁾ which indicates that carrying out lifestyle interventions at an early age has positive long-term effects, such as greater awareness and basic

knowledge on the subject, thus reducing the risk of non-communicable diseases in adulthood. Among the limitations of the study we have the size of the sample and its selection, remember that the results obtained in this article are particular to the 8 individuals analyzed, and in order to extrapolate these results to a larger reference population it would be necessary to choose subjects at random using probability sampling techniques, choosing people of different ages, socioeconomic strata, gender, among others. This becomes difficult because it would imply having a source of funding so that the availability of economic resources does not generate a sample selection bias, in this study and in the MEV program analyzed, patients self-finance their participation.

Since there are few cases in this study, the statistical tests require a greater difference to be able to establish that this is statistically significant; the sample size may also be hiding the fact that other dimensions may show improvement in their levels, but this is not large enough to be considered significant given the greater standard error of the sample mean.

CONCLUSION

In conclusion, there is an improvement in some variables measured after taking the "Lifestyle Medicine" reversal program compared to baseline measures in the 8 patients monitored for 8 weeks. These were weight, BMI, glucose, glycosylated hemoglobin, triglycerides, urea and TGP.

An intervention with more patients is recommended in order to improve the statistical significance of the tests and to have more robust conclusions that can be extrapolated to the general population.

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Conflicts of Interest: One of the authors was a patient in a reversal program and is one of the eight cases studied.

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