Original Article

Therapeutic Inertia in Patients with Uncontrolled Type 2 Diabetes Mellitus

Inercia terapéutica en pacientes con diabetes mellitus tipo 2 descontrolada

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Summary

Objective: to analyze therapeutic inertia in patients with uncontrolled type 2 diabetes mellitus in a Family Medicine unit. **Methods:** analytical cross-sectional study conducted in a Family Medicine unit in Acapulco, Mexico. 255 records of uncontrolled patients with a diagnosis of type 2 diabetes mellitus were included, by non-probabilistic convenience sampling, from January to February 2023. The source of information was the medical record and laboratory database to obtain sociodemographic, clinical, anthropometric, and biochemical information. Medical records were reviewed to assess whether the physician changed the pharmacological treatment after the laboratory results. The seniority and training of the physician were obtained from the Coordination of Health Education and Research. Descriptive statistics, bivariate analysis by Mantel-Haenszel X^2, and logistic regression were performed on the data obtained. A value of p<0.05 and 95% CI was considered statistically significant. **Results:** the incidence of therapeutic inertia (TI) was 85.9% (n= 219), 67.8% (n= 173) of the medical staff attended at least one face-to-face or online training course on diabetes mellitus. Being <60 years of age (ORa 2.99, 95% CI 1.40-6.39, p 0.002) increased the likelihood of therapeutic inertia. **Conclusion**: Eight out of ten patients with uncontrolled diabetes mellitus presented therapeutic inertia. It is important to raise awareness and promote an integral approach in which the patient, physician, and institution actively participate, and synergistically to achieve adequate metabolic control.

Keywords: Type 2 Diabetes Mellitus, Therapeutic Inertia, Glycemic Control, Primary Care, Glycosylated Hemoglobin

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Received: 09/11/2023
Accepted: 01/29/2024

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Suggestion of quotation: Suastegui-Hernández LF, Vargas-Aragón R, Lagarza- Moreno AJ, Rodríguez-Jaimes A, Joanico-Morales B, Suástegui-Hernández JJ, Sánchez-Vicente E, Sosa-Martínez MJ. Therapeutic Inertia in Patients with Uncontrolled Type 2 Diabetes Mellitus. Aten Fam. 2024;25(2):68-74. http://dx.doi.org/10.22201/fm.14058871p.2024.287949

Aten Fam. 2024;25(2):68-74.http://dx.doi.org/10.22201/fm.14058871p.2024.287949

Resumen

Objetivo: analizar la inercia terapéutica en pacientes con diabetes mellitus tipo 2 descontrolada en una unidad de medicina familiar. **Métodos:** estudio transversal analítico, realizado en la Unidad de Medicina Familiar en Acapulco, México. Se incluyeron 255 expedientes de pacientes en descontrol con diagnóstico de diabetes mellitus tipo 2, mediante muestreo no probabilístico por conveniencia, de enero a febrero 2023. La fuente de información fue el expediente clínico y base de datos de laboratorio, para obtener información sociodemográfica, clínica, antropométrica y bioquímica. Se revisaron las notas médicas, para evaluar si el médico realizó alguna modificación en el tratamiento farmacológico posterior a los resultados de laboratorio. La antigüedad y capacitación del médico se recabó de la Coordinación de Educación e Investigación en Salud. Con los datos obtenidos se realizó estadística descriptiva, análisis bivariado por X^2 de Mantel-Haenszel y regresión logística. Se consideró un valor de $p<0.05$ e IC 95% como estadísticamente significativo. **Resultados:** la frecuencia de inercia terapéutica (IT) fue 85.9% (n= 219), 67.8% (n= 173) del personal médico realizó por lo menos un curso de capacitación de forma presencial o en línea sobre diabetes mellitus. Tener <60 años de edad (ORa 2.99, IC 95% 1.40-6.39, p 0.002) aumentó la posibilidad de presentar inercia terapéutica. **Conclusión:** ocho de cada diez pacientes con diabetes mellitus descontrolada, presentó inercia terapéutica. Es importante sensibilizar y promover un enfoque integral en el que el paciente, médico e institución participen de forma activa y sinérgica con el objetivo de alcanzar un adecuado control metabólico.

Palabras clave: diabetes mellitus tipo 2, inercia terapéutica, control glucémico, atención primaria, hemoglobina glicosilada

Introduction

Type 2 diabetes mellitus (DM2) is a global public health problem because, if not adequately controlled, it can lead to various micro- and macrovascular complications, disability, and premature death.[1,2] The International Diabetes Federation estimates that 10.5% (537 million) of adults aged 20-79 lived with this condition in 2021. This number could increase to 11.3% (643 million) by 2030.[3] In Mexico, the prevalence of diabetes increased from 14.4% to 18.3% (14.6 million) between 2006 and 2022.[4,5] The Mexican Institute of Social Security (IMSS) reported an incidence rate of 269.23 new cases per 100,000 patients, and a mortality rate of 48.0 per 100,000 in 2019.[6]

The lack of adequate therapeutic adjustment in patients with diabetes mellitus has a negative impact on glycemic control, which affects their quality of life.[7] Therapeutic inertia is mainly observed in patients with chronic degenerative diseases and is defined as the lack of treatment or its intensification when the patient does not respond adequately to previous treatment.[8-10]

50% of the factors involved in therapeutic inertia are physician-related, including lack of training, timely follow-up, consultation time, and resources. Patient-related factors account for 30% (medication side effects, polypharmacy, non-adherence, denial of illness, poor doctor-patient relationship, psychiatric illness, depression, substance abuse, lifestyle, low socioeconomic, and educational level), and finally, the health care system accounts for 20% (poor medical records, saturated agendas, lack of infrastructure, and supplies, and poor communication between physicians and administrators).[11-15]

A study in the United States of patients with DM2 reported a prevalence of 73% among physicians, with older age and polypharmacy being the main factors associated with therapeutic inertia.[16]

Therapeutic inertia leads to poor control of the risk of acute and chronic complications of the primary disease, with significant implications for patient health and increased health care costs. Therefore, specific strategies are needed to avoid clinical stagnation and patient non-adherence.[17]

Continuing education of health care professionals improves the therapeutic approach to patients with diabetes and increases the knowledge and confidence of health care professionals. Patients should be informed about the importance of treatment and guided in decision making to prevent complications.[8,17]

Against this background, the aim of the present study was to estimate therapeutic inertia in patients with uncontrolled type 2 diabetes mellitus in a primary care unit.

Methods

An analytical cross-sectional study was conducted from January to February 2023, based on information from the records of persons with uncontrolled type 2 diabetes mellitus who were seen at the outpatient clinic of the Family Medicine Unit (UMF) No. 9 of the IMSS (Mexican Institute of Social Security) in Acapulco, Guerrero, Mexico. Patient records were included with monthly attendance during January to July 2021, who had at least two medical attentions after

the report of laboratory studies, which had to be ≤6 months, of both genders, age ≥20 years, time of diagnosis of DM2 ≥1 year, with glomerular filtration rate (GFR) ≥60 ml/min/m2. Patients with psychiatric disorders, pregnant women, patients with sequelae of cerebral vascular events, history of hospitalization for acute complications one month prior to consultation, and having been seen in the *DiabetIMSS* Service were excluded. Patients with incomplete records that did not have basic, and sufficient study variables were excluded from the study. Sample size calculation was not performed because all records of patients with a confirmed diagnosis of uncontrolled DM2 who met the inclusion criteria were reviewed.

A questionnaire designed and completed by the researchers was used to collect patient information. The questionnaire contained four sections: sociodemographic information, clinical information, anthropometric parameters, and laboratory studies. The first section included age, gender, education, marital status, and occupation. The second section recorded the time of the DM2 onset, comorbidities, complications, and medications used in the management of diabetes mellitus. The third section recorded weight, height, body mass index (BMI), and blood pressure. Finally, the fourth section collected biochemical tests such as fasting glucose, glycosylated hemoglobin (HbA1c), creatinine; GFR was calculated with the Cockcroft-Gault formula, total cholesterol, C-LDL, C-HDL, triglycerides were classified according to the criteria defined by the Third Report of the National Cholesterol Education Program Expert Panel (NCEP-ATPIII).[18]

Fasting plasma glucose, and HbA1c levels were taken into account according to the control targets recommended by clinical practice guidelines (CPGs), or therapeutic algorithms for diabetes mellitus to establish the diagnosis of glycemic dysregulation.[1,19] Therapeutic inertia was determined when the physician did not change the pharmacological treatment, using the following formula: number of patients whose pharmacological treatment was not changed / number of patients who did not reach the control target x 100.[11]

The age, gender, medical education, and seniority of the family physician were obtained from the nominal records of the Coordination of Health Education and Research of FMU No. 9, corresponding to the period from January to December 2020.

Data were collected and analyzed using CIETmap 2.1.[20] Simple frequencies and percentages were calculated for qualitative variables, while measures of central tendency and dispersion were

Table 1. Distribution of Clinical and Anthropometric Variables in Patients with Uncontrolled Type 2 Diabetes Mellitus

	Variable	Frequency(n= 255)	Percentage
Aggregate comorbidities	Arterial Hypertension	165	64.7
	Dyslipidemia	192	75.3
	Overweight/obesity	213	83.5
	Venous insufficiency	21	8.2
	None	6	2.4
Time of diabetes mellitus diagnosis	5 to 10 years	235	92.2
	11 to 30 years	19	7.5
	>30 years	1	0.4
Chronic complications	Diabetic retinopathy	4	1.6
	Diabetic Neuropathy	21	8.2
	Diabetic foot	1	0.4
	None	232	90.1
Pharmacologic treatment	Metformin	217	85
	Acarbose	65	25.4
	Glibenclamide	71	27.8
	Insulin	111	43.5
	Pioglitazone	25	9.8
	DPP4	98	38.4
	SGLT2	1	0.4
Blood Pressure	Uncontrolled (>130/80 mmhg)	16	6.3
	Controlled (≤130/80 mmhg)	149	58.4
	Normal blood pressure	90	35.3
Body mass index	Overweight	106	41.6
	Obesity grade 1	61	23.9
	Obesity grade 2	29	11.4
	Obesity grade 3	15	5.9
	Normal weight	44	17.3

calculated for quantitative variables. To contrast the research hypothesis, the Kolmogorov-Smirnov test was used to define the distribution of the data. Bivariate analysis was performed to estimate odds ratios (OR), and Mantel-Haenszel X^2. A value of p<0.05 or 95% confidence interval (95% CI) with the Miettinen test was considered statistically significant. Logistic regression was used to determine the association of independent variables with therapeutic inertia.

The research protocol was approved by the local research committee and complies the current IMSS regulations.

Results

The age of the study population ranged from 21 to 80 years, with a median of 60 years, and a mean of 57.94 (SD ±11.27). 59.2% (n= 141) were women, and 40.8% (n= 104) were men, 59% (n= 151) had completed elementary school. Regarding work activity, 48.6% (n= 124) reported being employed, and 69.8% (n= 178) reported being married. 97.6% (n= 249) had one or more comorbidities, according to the time of development of DM2, 92.2% (n= 235) had five to ten years of diagnosis, average of ten years, interquartile range five years (5-10). Overweight was detected in 41.6% (n= 106). 85% (n= 217) of patients were receiving metformin as their main oral hypoglycemic agent. Clinical and anthropometric characteristics are shown in Table 1.

Mean fasting glucose 196.65 mg/dL, HbA1c 9.46%, systolic blood pressure 120.96 mmHg, diastolic blood pressure 75.55 mmHg, BMI 30.02 m2 were calculated, the rest of the anthropometric, and biochemical characteristics are described in detail in Table 2.

Table 2. Anthropometric and Biochemical Profile of Patients with Uncontrolled Type 2 Diabetes Mellitus (n= 255)

Variable	Mean	Median	Mode	Standard Deviation	Minimum	Maximum
Systolic blood pressure	120.96	120	120	8.73	100	180
Diastolic blood pressure	75.55	80	80	5.47	70	100
Weight	76.60	74.4	68	16.56	47.5	138
Body mass index	30.02	29.09	27.41	5.29	20.02	47.86
Fasting glucose	196.65	173	149	60.41	131	406
Glycosylated hemoglobin	9.46	9	7.4	1.93	7	14.8
Cholesterol	183.52	182	183	39.57	85	318
C-HDL	42.73	41.6	47	9.63	24.1	76.6
C-LDL	105.41	102	96	37.59	22	386
Triglycerides	195.82	171	112	146.93	45	1930
Creatinine	0.77	0.75	0.64	0.19	0.42	1.57
Glomerular filtration rate	108.83	98.63	84.62	40.73	60.06	330.56

Table 3. Distribution of Lipid Profile According to NCEP-Atpiii in Patients with Uncontrolled Type 2 Diabetes Mellitus

	Variable	Frequency (n= 255)	Percentage
Total Cholesterol	Desirable TC: <200 mg/dl	169	66.3%
	Borderline high TC: 200-239 mg/dL	64	25.1%
	Hight TC: ≥240 mg/dl	22	8.6%
C-HDL	Low C-HDL: <de 40 mg/dl	107	42.0%
	High C-HDL: ≥60 mg/dl	14	5.5%
	Normal C-HDL: 40-59 mg/dl	134	52.5%
C-LDL	C-LDL optimal: <100 mg/dl	120	47.1%
	C-LDL greater than optimal: 100- 129 mg/dL	73	28.6%
	Borderline high C-LDL: 130-159 mg/dL	47	18.4%
	High C-LDL: 160-189 mg/ dL	12	4.7%
	Very high C-LDL: ≥190 mg/dL	3	1.2%
Triglycerides	Normal TG: <150 mg/dL	102	40.0%
	Borderline high TG: 150-199 mg/dL	64	25.1%
	High TG: 200-499 mg/dL	84	32.9%
	Very high TG: ≥500 mg/dL	5	2.0%

Table 4. Bivariate Analysis of Factors Associated with the Presence of Therapeutic Inertia in Patients with Uncontrolled Type 2 Diabetes Mellitus

Variable	Categories	Therapeutic Inertia		ORna*	IC 95%**	p*** Value
		Yes	No			
Age	21-59 years	115	9	3.32	1.54-7.16	0.00
	≥60 years	104	27			
Gender	Male	92	12	1.45	0.69-3.04	0.36
	Female	127	24			
Schooling	Basic (illiterate, elementary, and middle school)	126	25	0.60	0.28-1.27	0.20
	High school and College	93	11			
Occupation	Unpaid	105	17	1.03	0.51-2.09	1
	Paid	114	19			
Marital status	Without spouse	46	8	0.93	0.40-2.18	0.83
	With spouse	173	28			
BMI	Overweight/obesity	185	26	2.09	0.94-4.68	0.09
	Normal weight	34	10			
Cholesterol	Hypercholesterolemia	75	11	1.18	0.55-2.54	0.71
	Desirable CT	144	25			
C-LDL	Optimal C-LDL	55	7	1.39	0.58-3.35	0.54
	Elevated C-LDL	164	29			
C-HDL	Optimal and elevated C-HDL	93	14	1.16	0.56-2.39	0.72
	Low C-HDL	126	22			
Triglycerides	Hypertriglyceridemia	137	16	2.09	1.03-4.22	0.04
	Normal triglycerides	82	20			
IFG	60 a 89 ml/min/1.73m2	83	136	0.49	0.24-0.99	0.07
	≥90 ml/min/1.73m2	20	16			
Physician's gender	Male	77	12	1.08	0.51-2.29	1
	Female	142	24			
Physician's work shift	Evening	133	20	1.24	0.61-2.52	0.59
	Morning	86	16			
Training	No	71	11	1.09	0.51-2.34	1
	Yes	148	25			
Seniority	16 to 30 years	98	17	0.91	0.45-1.84	0.85
	1 to 15 years	121	19			

*ORna: Unadjusted Odds Ratio, **CI 95 %: 95% Miettinen Confidence Interval, ***p Value

Regarding the type of dyslipidemia, hypercholesterolemia was found in 33.7% (n= 86), hypoalphalipoproteinemia in 42% (n= 107), elevated LDL-C (borderline to very high) in 24.3% (n= 62), and hypertriglyceridemia in 60% (n= 153) (Table 3).

Regarding the characteristics of the family physicians, 65.1% (n= 166) were women, followed by 34.9% (n= 89) men. According to the working shift, 60% (n= 153) worked in the evening, and 40% (n= 102) in the morning. 67.8% (n= 173) of the physicians completed at least one diabetes mellitus-related classroom or online training course in the last 12 months prior to the follow-up visit of the patient with uncontrolled DM2, while 32.2% (n= 82) received no training.

43.9% (n= 112) of the physicians reported 1-10 years of experience, 36.5% (n= 93) 11-20 years, and 19.6% (n= 50) 21-30 years, of which 95.3% (n= 243) were permanent workers and only 4.7% (n= 12) were temporary.

According to patient gender, therapeutic inertia was calculated in 84.1% (n= 127) of the females, and 88.5% (n= 92) of the males. The overall frequency of therapeutic inertia was 85.9% (n= 219).

Bivariate analysis identified two factors associated with therapeutic inertia in patients with uncontrolled type 2 diabetes mellitus: age <60 years and hypertriglyceridemia (Table 4).

Bivariate Analysis of Factors Associated with the Presence of Therapeutic Inertia in Patients with Uncontrolled Type 2 Diabetes Mellitus

In the logistic regression analysis, adjusted for age and hypertriglyceridemia, it was observed that age under 60 years (ORa 2.99, 95%CI 1.40-6.39, p 0.002) maintained a statistically significant association with the presence of

therapeutic inertia, being consistent in the adjusted model, which did not occur with hypertriglyceridemia (ORA 1.81, 95%CI 0.90-3.65, p 0.12).

Discussion

According to the World Health Organization, the direct costs of complications caused by poor diabetes control are three to four times higher than in those who achieve glycemic targets.[21]

The frequency of therapeutic inertia observed in this study in both genders was higher than that reported by various authors at international and national levels.[9,16,22-27] These differences may be explained by the nature of the population, the inclusion criteria used, the epidemiologic design, and the sample size.

It was observed that nine out of ten people had at least one other comorbidity in addition to diabetes mellitus, as well as a time of diagnosis of the disease between five and ten years, which is a risk factor for most cardiometabolic events.[17] These results are consistent with those observed in Spain, as reported in previous studies,[22,27] but show differences in the incidence of chronic complications compared to the study by Cuevas-Fernández et al.[27].

The main oral hypoglycemic agent prescribed by health personnel was a biguanide (metformin 850 mg), which is in agreement with other authors, as it is one of the first lines of defense.[25,27]

In the multivariate analysis, it was found that being younger than 60 years of age was associated with therapeutic inertia, which differs from what has been reported in other cross-sectional studies in the Spanish population.[16,23,27] It has been described that younger age is a relevant factor for therapeutic inertia, perhaps due to fear of possible adverse effects of the drugs or the risk of hypoglycemia, so that older patients might have better therapeutic adherence than younger patients.[11,28] Other authors have not found an association with this study variable.[9,24,26]

No association was observed with the other patient and healthcare professional variables, such as training in diabetes mellitus and length of service, which is similar to what has been reported in the literature,[9,16,23] but contrary to what was found in another study conducted in a primary care health center.[27]

One of the limitations of this research was its design, as it is a cross-sectional study, it is subject to possible selection bias, as those who came for medical advice may have been motivated by lack of economic resources or discomfort. Another limitation was the lack of complete laboratory tests, requested by the physician, in accordance with the guidelines, due to the lack of supplies in the unit or the restrictions imposed by the COVID-19 pandemic. In addition, the temporality and selection of the sample confounded the association between exposure factors and effect, making it unrepresentative of the population and limiting the extrapolation of our results. It will be necessary to follow up the population with research studies with a higher level of evidence (cohort studies or controlled trials), and a larger sample size to establish causality.

One of the strengths of this study was that it was carried out in the family medicine unit with the largest number of beneficiaries in the delegation of the IMSS in Guerrero, and that it was one of the few studies carried out in Mexico that included both patient and physician variables. The effectiveness of the indications given to the population should be improved, with adherence to guidelines, therapeutic algorithms, and recommendations derived from evidence-based medicine, in order to have a greater impact on the health of the population.[21]

Conclusion

Eight out of ten patients with uncontrolled type 2 diabetes mellitus were found to have therapeutic inertia, which was significantly associated with patient age. It is therefore important to raise awareness and promote an integral, multidisciplinary approach in which the patient, the physician, and the institution participate actively and synergistically, with the aim of achieving adequate metabolic control that will have an impact on the health of the beneficiaries. Future research will need to look at a greater number of variables, such as adherence to treatment.

Authors' Contribution

LF S-H: Conceptual design, development, writing, data collection, data analysis, discussion of results, and preparation of the manuscript for publication. R V-A: design, development, writing, discussion of results, and preparation of the manuscript for publication. AJ L-M: design, development, writing, discussion of results, and preparation of the manuscript for publication. AJ L-M: conception, development, writing, data analysis, DIScussion of results, and preparation of the manuscript for publication. a r-j: design, development, writing, data analysis, DIScussion of results, and preparation of the manuscript for publication. b j-m: conception, development, writing, DIScussion of results, and preparation of the manuscript for publication. jj s-h: design, development, writing, DIScus-

sion of results, and preparation of the manuscript for publication. é s-v: design, development, writing, DISCussion of results, and preparation of the manuscript for publication. mj s-m: conception, development, writing, data analysis, discussion of results, and preparation of the manuscript for publication. All authors have critically reviewed the manuscript and approved its submission for pu**b**lication.

Funding Information

This research received no external funding.

Conflicts of interest

The authors declare not having conflict of interests.

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