Original Article

Revista de Enfermagem do Centro-Oeste Mineiro
2023; 13/4993
www.ufsj.edu.br/recom

RECOM
Revista de Enfermagem do Centro-Oeste Mineiro

Adherence to good practice recommendations in insulin therapy: relationship with glycemic control

Adesão às recomendações de boas práticas em insulinoterapia: relação com o controle glicêmico

Adherencia a las recomendaciones de buenas prácticas en insulinoterapia: relación con el control glucémico

Abstract

Objective: To analyze the relationship between levels of adherence to good practice recommendations in insulin therapy and glycemic control metrics in patients with diabetes mellitus. **Methods:** A descriptive, cross-sectional and quantitative study was conducted with 102 patients with diabetes mellitus. Data collection occurred through semi-structured interviews and, in a complementary manner, with data obtained from medical records. Four collection instruments were applied: I) sociodemographic and clinical characterization form, II) recall of insulin therapy guidelines, III) capillary glycemia self-monitoring record sheet and IV) glycemic control assessment metrics record form. **Results:** There was a statistically significant association between the level of non-adherence (100%) to insulin therapy recommendations and estimated target time ≤ 70%, as well as between 80% non-adherence and standard deviation ≥ 50 mg/dl. **Conclusion:** These findings validate that non-adherence to the recommendations of good insulin therapy practices contributes to glycemic unmanageability.
Descriptors: Cooperation and Adherence to treatment; Good handling practices; Insulin; Glycemic control.

Resumo

Objetivo: Analisar a relação entre os níveis de adesão às recomendações de boas práticas em insulinoterapia e as métricas de controle glicêmico em pacientes com diabetes mellitus. **Métodos:** Estudo descritivo, transversal e quantitativo, realizado com 102 pacientes com diabetes mellitus. A coleta de dados ocorreu por meio de entrevista semiestruturada e, em caráter complementar, com dados obtidos dos prontuários. Aplicaram-se quatro instrumentos de coleta: I) formulário de caracterização sociodemográfica e clínica, II) recordatório de orientações sobre insulinoterapia, III) folha de registro da automonitorização da glicemia capilar e IV) formulário de registro das métricas de avaliação do controle glicêmico. **Resultados:** Houve associação estatística significativa entre nível de não adesão (100%) às recomendações em insulinoterapia e tempo no alvo estimado ≤ 70%, assim como entre 80% de não adesão e desvio padrão ≥ 50 mg/dl. **Conclusão:** Esses achados validam que a não adesão às recomendações de boas práticas de insulinoterapia contribui para o descontrole glicêmico.
Descritores: Cooperação e Adesão ao tratamento; Boas práticas de manipulação; Insulina; Controle glicêmico.

Resumen

Objetivo: Analizar la relación entre los niveles de adherencia a las recomendaciones de buenas prácticas en insulinoterapia y las métricas de control glucémico en pacientes con diabetes mellitus. **Métodos:** estudio descriptivo, transversal y cuantitativo, realizado con 102 pacientes con diabetes mellitus. Para la recolección de datos se utilizaron entrevistas semiestructuradas y, de forma complementaria, se obtuvieron datos de las historias clínicas. Se aplicaron cuatro instrumentos de recolección: I) formulario de caracterización sociodemográfica y clínica, II) recordatorio de pautas de insulinoterapia, III) formulario de autocontrol de glucemia capilar y IV) formulario de registro de métricas de evaluación del control glucémico. **Resultados:** hubo una asociación estadísticamente significativa entre el nivel de no adherencia (100%) a las recomendaciones de insulinoterapia y el tiempo estimado ≤ 70%; así como entre el 80% de no adherencia y la desviación estándar ≥ 50 mg/dl. **Conclusión:** estos hallazgos evidencian que la no adherencia a las recomendaciones de buenas prácticas de insulinoterapia contribuye a la falta de control glucémico.
Descriptores: Cumplimiento y Adherencia al Tratamiento; Buenas Prácticas de Manipulación; Insulina; Control Glucémico.

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INTRODUCTION

At present, global projections reveal Diabetes mellitus (DM) as a pandemic, affecting people regardless of their age and socioeconomic condition, and constituting a challenging public health problem of the 21st century. This impact on health systems is the result of the high prevalence of the disease and the morbidity and mortality associated with micro and macrovascular complications[1].

The prevalence of DM is increasing rapidly, surpassing the prevalence of any other health condition in recent decades; global studies estimate that by 2030 there will be 643 million cases of the disease and 783 million by 2045. In Brazil, estimates indicated 15.7 million adults with DM in 2021, leading the country to the first position in Latin America in numbers of cases and sixth place in the world ranking. Future projections indicate that by 2045 this rate will increase to the order of 23 million people living with diabetes in the country[2].

The person affected by a chronic endocrine-metabolic disorder requires multiprofessional attention due to its complex clinical management, characterized by the growing demand for strategic innovations in diabetes care necessary to modulate the multifactorial interaction that interferes with glycemic control and contributes to the significant prevalence and morbidity and mortality rates of the disease. Thus, the management of DM is optimized through the implementation of interventions directed to appropriate practices of activities directly linked to the self-care of patients in insulin therapy[3].

The main worrying factor in the health care of people with diabetes is the chronicity of the disease associated with micro and macrovascular complications that arise over time when there is no adequate self-management of the therapeutic plan. In this perspective, the treatment of DM is not restricted to medication management, nor to the process of evaluating adherence to medication treatment, being significant for better metabolic outcomes to evaluate and stimulate the promotion of adherence to the safe practice of self-administration in insulin therapy[4].

In the area of health, professionals provide instructions on the behaviors that patients must issue in the management of their health problem – the issuance of these prescribed behaviors is called adherence to treatment. According to the World Health Organization (WHO), adherence to treatment is the degree of agreement of the patient with the recommendations of health professionals, transcending to the extent of compliance not only with medication guidelines, but also with non-pharmacological measures such as follow-up of changes in life habits, namely: diet, physical activity, smoking and alcohol cessation, sleep patterns, leisure, social and practical skills[5].

In the case of DM, adherence to compliance with the guidelines on insulin therapy and other care pertinent to the handling, conservation and disposal of insulins are essential to achieve better clinical outcomes that are reflected in better glycemic control and prevention of the emergence of acute and chronic complications. Good adherence is understood as the agreement and follow-up of at least 80% of the pharmacological treatment, as well as other care prescribed/recommended by health professionals[6-7].

Thus, the different therapeutic approaches of diabetes have as common and guiding link the educational process in health, considering that, in many clinical situations, the treatment requires complex therapeutic regimens such as full insulin therapy in multiple daily doses. This postulates interventions focused on promoting adherence to insulin management through agreement and implementation of guidelines in good practices, which, supported by levels of scientific evidence, will translate the strength of the recommendations to allow safe and consistent practices, enabling an increase in survival and improvement in the quality of life of people with diabetes[8].

As presented in the literature, many studies show distinct obstacles related to the correct management in insulin therapy and,

consequently, obstacles in metabolic control in the short and long term. Such obstacles focus on errors and inaccuracies in the technique of administration, storage, correct use and rotation of injection and disposal sites of sharps[1,9-10-11-12-13]. Thus, it is relevant to study the theme in question, since not only the direct adherence to self-care in diabetes focusing on the application or omission of prescribed insulin doses is important, but also adherence to the recommendations of safe practice in the execution of the procedure, ensuring greater safety and efficacy in compliance with insulin self-administration, which, in turn, confers greater accuracy of glycemic control.

The development of this study is based on the demand for educational and care strategies, necessary to expand the theoretical and evaluative framework, which aim to optimize the adherence of patients with diabetes to the execution of self-care activities in insulin therapy as recommended. Considering that the deficit of adherence to good practices in insulin therapy can interfere with glycemic variability (GV) and glycated hemoglobin (HbA1c) above the target.

The relevance of the study comes from obtaining results on technical processes used in the practice of insulin therapy, which are relevant to determine the influence of these processes on the glycemic status of patients who self-administer insulin, driving the increase of new research focused on adherence to compliance with recommendations on good practices in storing, preserving, preparing and applying insulin, instructed in agreement with the professional nurses during nursing consultations in diabetes. In view of this, the literature shows significant gaps between the recommendations of good practices in insulin therapy and the current practice performed by many patients[10].

Benefits for clinical and social practice are also emphasized, respectively, in the context of acquiring new knowledge about the direct and/or indirect relationship of safe practices in insulin therapy in the extension of glycemic control, offering subsidies for the development of various technologies with a view to solving practical problems related to this activity of self-management of DM and in the social context of promoting the empowerment of people with diabetes, optimizing their role in the identification and correction of technical failures in insulin therapy during the process of evaluation, guidance and education in diabetes developed by nurses working in this area.

Thus, considering the relevance and benefits of the present study, the investigation process of the research object began with the guiding question: is it known the relationship of the influence of practical and technical ways in insulin therapy on glycemic control, but how much does the level of adherence to the recommendations of good practices in insulin therapy interfere with the glycemic control metrics of patients on insulin therapy who perform self-administration? From this, the objective of the study was to analyze the relationship between the levels of adherence to the recommendations of good practices in insulin therapy and the metrics of glycemic control in patients with DM.

METHODS

The scientific design of the study is descriptive and cross-sectional with a quantitative approach, systematized through methodological rigor for observational studies in epidemiology based on the checklist verification of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline, hosted in the Enhancing the Quality and Transparency Of Health Research (EQUATOR) network.

The study was conducted at the Department of Endocrinology and Diabetes (DED) of a university hospital (UH), located in Fortaleza, Ceará. It consists of a tertiary referral outpatient unit of this hospital complex, specialized in the clinical and therapeutic follow-up of several endocrinopathies, including DM, providing care coverage to referral patients of the Primary

Health Care Unit (PHCU) of Fortaleza and other municipalities of Ceará, as well as referrals from other Brazilian states.

The DED is composed of nurses and medical specialists, respectively, diabetologists and endocrinologists. In addition, the provision of assistance to people with diabetes in the DED is exercised directly by residents of the multi-professional integrated residency program in diabetes (nurses, nutritionists and physical therapists) and by medical residents of the medical residency program in endocrinology.

The study participants were patients diagnosed with DM assisted in the DED, selected for sample composition through the following eligibility criteria: I) patients ≥ 18 years of age diagnosed with type 1 DM, type 2 DM or other types of diabetes followed up in the DED; II) patients on insulin therapy who perform self-administration of insulin; III) patients with inputs to perform self-monitoring of capillary glycemia (SMCG) and IV) patients with preserved cognitive function to understand, verbalize and answer questions during the interview stage. Participants diagnosed with Gestational Diabetes Mellitus (GDM) and those undergoing insulin therapy through the continuous insulin infusion system (CIIS) were excluded from the sample.

The sample size, composed of 102 patients, was defined using the non-probabilistic and non-random sampling technique for convenience. The recruitment process of the participants occurred through the approach of patients who were in the service for the usual day of a previously scheduled consultation, at which time they were invited to participate in the study, by presenting the objectives and relevance of the research through the reading and granting of the Informed Consent Form (ICF).

Data collection took place between June and August 2022 through the use of two collection techniques: semi-structured interview and, in a complementary manner, survey, review and recording of secondary data obtained from the patients' physical and/or electronic records.

Initially, for data acquisition, four collection instruments were applied at the interview stage: I) sociodemographic and clinical characterization form, II) recall instrument for guidance on insulin therapy, III) record sheet for SMCG notes and IV) record form for glycemic control assessment metrics. Instruments II, III and IV were organized and semi-structured according to the recommendations of the guidelines of the Brazilian Diabetes Society (BDS).

However, it was difficult to obtain complete data at the time of the interview, as the patients did not present recent laboratory tests and/or SMCG records. This required the complementation of the information in a second moment, through the search for data in medical records, accessed through the electronic care system, evaluation and evolution of patients followed in the DED. The time interval for collecting additional data in medical records was based on the rigorous determination of a specific time so as not to differ from the objectives proposed in the study, delimiting time deviation from 6 months to 1 year before the time of current data collection.

Box 1 shows the description of the variables selected for the study by collection instrument, as well as the composition and purpose of each one.

Box 1 – Presentation of the collection instruments (forms) and study variables.

SOCIODEMOGRAPHIC AND CLINICAL CHARACTERIZATION OF ADULT PATIENTS	
Composition/purpose	It consists of a 15-item instrument to characterize the study participants regarding sociodemographic, clinical and behavioral aspects related to lifestyle habits.
Descriptive variables	Age, gender, education, occupation, family income, physical activity, diet, alcohol consumption, smoking, type of DM, time since diagnosis of DM, comorbidities associated with DM, chronic microvascular complications, oral and injectable medications in use.

(Continue)

RECALL OF GUIDELINES ON INSULIN THERAPY	
Composition/purpose	It is an instrument composed of actions and guidelines on stages of insulin therapy care, provided during nursing consultations as a process of education in good practices in insulin therapy, promoting self-care in self-administration of insulin; structured in 19 items with dichotomous answers yes or no.
Independent variables	Adequate storage, adequate transport, time of removal of insulins from the refrigerator, cleaning the seal of insulin bottles/pens, homogenization of insulin NPH, order of insulin aspiration, cleaning the skin with alcohol before application, flow test, application of insulin in recommended places, suspension of application in places with skin changes, rotation of the administration site, interval of time between application and meal, performs subcutaneous fold, angles the application correctly, waits the time of 10 seconds to remove the needle from the subcutaneous after application, stores pens with needles connected after use, reuses syringes and needles, performs cleaning of needles and proper disposal of sharp materials used at home. From the processing of these variables, the independent variables were generated: levels of adherence to recommendations in insulin therapy (total adherence, partial adherence and non-adherence).
RECORD SHEET FOR SMCG NOTES	
Composition/purpose	It consists of the instrument for transferring the glycemic values obtained by patients at home, in general, indicating the performance of six glycemic measurements daily, in the pre- and post-prandial period of the main meals of the day (breakfast, lunch and dinner).
Variables	Values of the capillary glycemic curve performed and recorded by patients for evaluation of glycemic control.
RECORD OF GLYCEMIC CONTROL EVALUATION METRICS	
Composition/purpose	An instrument composed of 5 items for the acquisition of the study outcome variables related to the glycemic control evaluation metrics, obtained through laboratory tests and the glycemic record performed by the SMCG.
Dependent variables (outcome)	Fasting glycemia (FG), postprandial glycemia (PPG), glycated hemoglobin (HbA1c), estimated time in target/time in range (TIR) and standard deviation (SD).

Source: Own elaboration.

The organization and consolidation of the data analytical process took place through the collection, insertion and tabulation of the data directly in the Research Electronic Data Capture (REDCap) system. Such a system is a secure software platform, designed to support online search and database management, which provides intuitive interface for validated data capture; audit trails for screening data manipulation; continuous automated data export procedures for common statistical packages and procedures for data integration and interoperability with external sources[14].

The database of this research was imputed and transported for analysis in the Statistical Package for the Social Science (SPSS) version 22.0. The data were grouped into measures of central tendency and dispersion, presented in tables, containing the absolute and relative frequencies. Variable analysis was considered statistically significant with p values ≤ 0.05 and Fisher's exact statistical test was used to analyze the association between variables.

According to the concept of adherence, which consists of compliance with at least 80% of the care plan offered[6], the level of adherence to the guidelines provided by nurses on insulin therapy care was categorized based on the percentage calculation of affirmative answers. In view of this, we proceeded with the ratio between the number of "yes" answers over the total number of 19 items evaluated, multiplying the quotient of this ratio by 100, obtaining as a result the percentage of the level of adherence to the recommendations of good practices in insulin therapy, categorized into three levels: non-adherence, partial adherence and total adherence.

Although this categorization does not have specific cutoff points and/or validated in the literature in the aspect of adherence to the recommendation of good insulin therapy practices, it was decided to categorize into three levels of adherence based on 4 bases: I) optimize the analytical process of the bivariate

association between the independent variables with the outcome variables, II) support the execution of the research in line with the proposed objectives, basing means to answer the research question, III) enable the increase of studies in the area of adherence, considering the original nature of the research and IV) establish cutoff points for this purpose, considering the complexity and particularity involved in the process of evaluating good practices in insulin therapy, according to the reference that supports the delimitation in three levels[6,10].

Thus, the levels of adherence to good practice recommendations in insulin therapy are **total adherence** (≥ 80% of affirmative answers, corresponding to 16-19 "yes" answers)[6], **partial adherence** (≥ 50% to < 80% of affirmative answers, corresponding to 10-15 "yes" answers) and **non-adherence** (< 50% of affirmative answers corresponding to 1-9 "yes" answers). Those with a percentage below 80% were subdivided as a significant statistical evaluation strategy (partial adherence and non-adherence)[10].

This research was produced based on the umbrella project entitled "Characteristics of a multifaceted approach to the health care process of people with diabetes mellitus", registered in Plataforma Brasil for the purpose of evaluation by the REC of the Walter Cantídio University Hospital (WCUH) and by the National Research Ethics Commission (CONEP), from which it received a favorable opinion under number 4,832,221 and CAAE number 46667721.3.0000.5045.

In addition, the development of the research was based in line with the regulations established in Resolution number 466/2012 of the National Health Council (NHC) that regulates the conduct of research with human beings. Therefore, all bioethical precepts were respected, complying with the references of autonomy, non-maleficence, beneficence, justice, equity and respect for the dignity of the human being.

RESULTS

The analysis of the sample (n = 102) allowed the characterization of the sociodemographic profile (Table 1) with a predominance of females 64 (63%), mean age of 50 years (± 17) and complete high school educational levels – 34 individuals (34%) – and incomplete elementary school – 32 individuals (31%) –, adding up to more than half of the individuals among the identified educational levels. As for occupation and family income, most are characterized as retired (43 individuals or 42%) and with earnings of 1 to 2 minimum wages (75 individuals or 74%).

Regarding behavioral characterization (Table 1), there was a predominance of sedentary lifestyle in 64 individuals (63%), following a healthy diet by 56 individuals (55%), denial of drinking habits by 50 individuals (49%) and smoking habits by 60 individuals (59%). However, 39 individuals (38%) were former smokers and 33 (32%) were former alcoholics.

Table 1 – Sociodemographic and behavioral characterization of DM patients under clinical follow-up in the DED of the UH, n = 102, Fortaleza (CE), 2022.

Variables	n (%)
Age (years)	50 ± 17 (53)[1]
Sex	
Female	64 (63%)
Male	38 (37%)
Education	
Illiterate	4 (4.0%)
Literate	3 (3.0%)
Incomplete elementary school	32 (31%)
Complete elementary school	6 (5.9%)
Incomplete high school	7 (6.9%)
Complete high school	34 (34%)
Incomplete higher education	4 (4.0%)
Complete higher Education	12 (12%)
Occupation	
Retired	43 (42%)
Student	3 (2.9%)
Unemployed	3 (2.9%)

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Variables	n (%)
Housewife	22 (22%)
Domestic employee	3 (2.9%)
Formal salaried worker	19 (19%)
Self-employed	9 (8.8%)
Family income	
Less than 1 minimum wage	13 (13%)
More than 1 to 2 minimum wages	75 (74%)
3 or more minimum wages	14 (14%)
Physical activity	
Yes	38 (37%)
No	64 (63%)
Healthy diet	
Yes	56 (55%)
No	46 (45%)
Alcoholism	
Yes	19 (19%)
No	50 (49%)
Former alcoholic	33 (32%)
Smoking	
Yes	3 (3.0%)
No	60 (59%)
Former smoker	39 (38%)

Source: Own elaboration. [1]mean ± standard deviation (median).

Regarding clinical characterization, the type of diabetes mostly found was type 2 DM, in 58 ind1ividuals (57%), with a diagnosis time of more than 10 years among 80 (78%) people in the sample. Dyslipidemia (DLP) was present in 69 (68%) participants, followed by Systemic Arterial Hypertension (SAH) in 54 individuals (53%). Regarding microvascular complications, neuropathy – in 33 individuals (32%) – and retinopathy – in 31 individuals (30%) – were prevalent.

Regarding pharmacological treatment, oral antidiabetics (OAD) 59 (58%), statins 74 (73%) and antihypertensives (AH) 54 (53%) were the main oral medication classes in use by patients; while among injectable medications, the prominent triad focuses on intermediate-acting human insulins, used by 61 individuals (60%), and fast-acting, used by 55 individuals (54%), supplementing with long-acting insulin analogue, used by 40 individuals (39%) (Table 2).

Table 2 – Clinical-therapeutic characterization of patients with DM under clinical follow-up in the DED of the UH, n = 102, Fortaleza (CE), 2022.

Variables	N (%)
Type of DM	
Type 1 DM	30 (29%)
Type 2 DM	58 (57%)
DM type LADA*	5 (4.9%)
DM type MODY†	1 (1.0%)
PTDM‡	6 (5.9%)
Other types of DM	2 (2.0%)
Time since diagnosis	
< 5 years	8 (7.9%)
5 to 10 years	14 (14%)
> 10 years	80 (78%)
Comorbidities associated with DM	
Systemic arterial hypertension	54 (53%)
Cardiovascular disease	9 (8.8%)
Cirrhosis	1 (1.0%)
Fatty Liver Disease	3 (2.9%)
Dyslipidemia	69 (68%)
Obesity	14 (14%)
Hypothyroidism	9 (8.8%)
Cancer	0 (0%)
No comorbidities	21 (21%)
Chronic microvascular complications	
Retinopathy	31 (30%)
Nephropathy	13 (13%)
Neuropathy	33 (32%)
Oral medications in use	
Antidiabetic agents.	59 (58%)
DPP-4 Inhibitors§	4 (3.9%)
SGLT2 Inhibitors	5 (4.9%)
Alpha-glucosidase inhibitors	0 (0%)
Statins	74 (73%)
Antihypertensives.	54 (53%)
Antineoplastic agents	0 (0%)
Levothyroxine – T4	9 (8.8%)
Immunosuppressants	9 (8.8%)

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Variables	N (%)
Injectable medications in use	
LPG Analogues – 1¶	3 (2.9%)
Intermediate-acting human insulin	61 (60%)
Fast-acting human insulin	55 (54%)
Ultra-fast-acting insulin analogue	37 (36%)
Long-acting insulin analogue	40 (39%)
Ultra-long-acting insulin analogue	0 (0%)

Source: Own elaboration. *LADA = Latent Autoimmune Diabetes in Adults. †MODY = Maturity Onset Diabetes of the Young. ‡PTDM = Post-transplant Diabetes Mellitus. §DPP – 4 = Dipeptidyl Peptidase Enzyme type 4. SGLT – 2 = Sodium and Glucose Cotransporter type 2. ¶GLP – 1 = Glucagon-like Peptide type 1.

Regarding the practice of compliance with insulin therapy care (Table 3), more than half of the sample – 66 patients (65%) – was categorized in the level of partial adherence to the recommendations of good practices in insulin therapy, corresponding to intermediate compliance of less than 80% of the step-by-step oriented to perform the insulin therapy practice safely and adequately, but not restricted to the cutoff point of less than 50%.

In the results of the comparative analysis of the level of adherence to the recommendations in insulin therapy with the glycemic control metrics, there was a statistically significant association of the level of adherence with the variables TIR (p = 0.037) and SD (p = 0.036). It is observed that patients classified as non-adherent (100%) to the recommendations on insulin therapy care had estimated TIR less than or equal to 70%. Regarding the outcome variable SD, 80% of those classified as non-adherent had SD equal to or greater than 50 mg/dl and 70% of patients with total adherence had SD less than 50 mg/dl (Table 3).

Although the relationship between the level of adherence to insulin therapy care and HbA1c did not present sufficient evidence of a statistically significant association in this research, the p-value identified (p = 0.073) showed an association with a significant difference between the findings studied, where 100% of those classified as non-adherence to good practices in insulin therapy showed HbA1c greater than or equal to 7% (Table 3).

Table 3 – Level of adherence to recommendations in insulin therapy among patients with DM undergoing clinical follow-up in the DED of the UH, according to outcome variables, n = 102, Fortaleza (CE), 2022.

Outcome variables	n	Total[1]	Level of adherence to recommendations in insulin therapy			P-value [2]
			Full adherence n = 25[1]	Partial adherence n = 66[1]	Non-adherence n = 11[1]	
Fasting glucose	**102**					**0.487**
< 100 mg/dL		13 (13%)	4 (16%)	9 (14%)	0 (0%)	
≥ 100 mg/dL		89 (87%)	21 (84%)	57 (86%)	11 (100%)	
Postprandial plasma glucose	**102**					**>0.999**
< 180 mg/dl		32 (31%)	8 (32%)	21 (32%)	3 (27%)	
≥ 180 mg/dL		70 (69%)	17 (68%)	45 (68%)	8 (73%)	
Glycosylated hemoglobin	**102**					**0.073**
< 7%		14 (14%)	1 (4%)	13 (20%)	0 (0%)	
≥ 7%		88 (86%)	24 (96%)	53 (80%)	11 (100%)	
Target time	**102**					**0.037**
≤ 70%		91 (89%)	25 (100%)	55 (83%)	11 (100%)	
> 70%		11 (11%)	0 (0%)	11 (17%)	0 (0%)	

(Continue)

Outcome variables	n	Total[1]	Level of adherence to recommendations in insulin therapy			P-value [2]
			Full adherence n = 25[1]	Partial adherence n = 66[1]	Non-adherence n = 11[1]	
Standard deviation	88*		**n = 20[3]**	**n = 58[3]**	**n = 10[3]**	**0.036**
< 50 mg/dL		49 (56%)	14 (70%)	33 (57%)	2 (20%)	
≥ 50 mg/dL		39 (44%)	6 (30%)	25 (43%)	8 (80%)	

Source: Own elaboration. [1]n (%); [2]Fisher's exact test. *Variable standard deviation with reduced n sample size resulting from the unfeasibility of access to data from 14 patients. [3]total n of the level of adherence considered for comparative analysis with standard deviation.

DISCUSSION

The discussion regarding statistical analyses between the levels of adherence to recommendations in insulin therapy with glycemic control metrics presents broad limitations for comparability with research results corresponding to the same theme and the same object of investigation of the current study. Such limitations are related to the scarcity of national and international studies that analyze insulin therapy care in a systematic manner and categorized into levels of adherence to the recommendations of good practices offered by health professionals – contemplating the skills and practices of insulin storage, safe way in the preparation and application of insulin injection and safe disposal of piercing-cutting waste – and its influence relationship on glycemic control.

This is an innovative research, starting from the perspective of originality in investigating other aspects related to adherence in the context of diabetes care, supplanting the various studies published in the literature on adherence to medication and non-medication treatment in DM. In short, due to these limitations, the discussion of the association between variables was made with adherence studies in general in the field of diabetes care and with those who analyzed the insulin injection technique and blood glucose control, but there was no relationship with categorization of adherence, but rather execution of the appropriate or inadequate technique. In addition, most adherence studies, when related to glycemic control, use HbA1c and fasting blood glucose as an evaluation metric of this control, not incorporating other glycemic evaluation metrics.

A study carried out in primary hospitals in Ethiopia proposed to evaluate the knowledge, skills and practices on insulin storage and insulin injection technique of 166 patients with DM. To evaluate the practice, the Likert scale was used with 56 total points, obtained from three classification levels: poor practice with a score < 50% of the total (< 28 points), regular practice 51 to 75% (29-42 points) and good practice > 75% (> 42 points). Among the results, it was identified that the majority of participants (64.5%) had regular practice. Comparably, the present study revealed the majority classified in the category of partial adherence to the recommendations of good practices in insulin therapy (≥ 50% to < 80% of positive responses). Thus, it is verified that the level of partial adherence involves a regular practice, since the intermediate observance of the instructions in insulin therapy does not make up the percentage necessary for total adherence to good practices[15].

In this study, there was a significant relationship between the level of non-adherence to recommendations in insulin therapy and the glycemic control evaluation metrics: estimated low TIR and high SD; as well as total adherence to good practices in insulin therapy and low SD. These findings imply that following the steps for the correct insulin injection technique and other associated insulin therapy care, as described and recommended by the guidelines of societies specialized in diabetes management, are relevant to ensure optimal insulin quality, administration, absorption, bioavailability and safety, optimizing blood glucose levels and mitigating GV[16].

These findings are corroborated by a study conducted at a diabetes research center in Iran to determine the association between the insulin

injection technique and blood glucose control in patients with type 2 DM; in the study, lower scores in the insulin injection technique (mean: 18.05 ± 3.53) correlated statistically significantly with elevated HbA1c levels (≥ 7.5%). It can be inferred that this feat is related to the correct practice of insulin injection in blood glucose control, which in turn allows extrapolating the interpretation to a context of patients' adherence to good practices related to insulin therapy care recommended by health professionals – because the higher the insulin injection score, the lower the HbA1c levels[17].

In addition, the referenced study revealed, through Pearson's test, a strong negative correlation between the levels of scores in insulin therapy and the glycemic control evaluation metrics (FG, GPP-2H and HbA1c) with a statistically significant difference; in other words, the increase in the score in the insulin injection technique generates a reduction in the values of FG (0.23), GPP-2H (0.16) and HbA1c (0.26). Thus, the authors of the study concluded that, although good practices in the execution of the steps in insulin therapy are known to be essential factors to ensure safety and efficacy in insulin replacement therapy and, consequently, successful metabolic clinical control, none of the patients in the study fully adhered to the principles of adequate practice in insulin therapy, and may result in pain during injection, subcutaneous changes such as lipohypertrophy, hyperglycemia and elevation of glycated hemoglobin[17].

Expert recommendations on appropriate and safe management of insulin therapy come from the results of the relevant multinational Injection Technique Questionnaire (ITQ) study, conducted with more than 13,000 patients in 42 countries. These recommendations were published by different national and international organizations in their guidelines on the technique of insulin injection and other care pertinent to the conservation, storage and transport of insulins, showing potential complications resulting from non-compliance with good practices in insulin therapy[12].

The insulin injection technique is a determining factor for short-term and long-term glycemic control, as corroborated in a study developed in the endocrinology department of a university hospital in China, which evaluated the relationship between GV and insulin therapy technique in patients with type 2 DM through 15 items related to insulin therapy care, ranging from the conservation aspects of insulins to the technical ability of self-administration, with a maximum score of 2 points for each item and an ideal total score for adequate insulin practice of 30 points. The specified study revealed a mean total score of the insulin therapy technique of the studied sample significantly lower than the score considered ideal for good technique (17.0 ± 4.4 vs. 30)[18].

Inferring this result for the intentional context of the present study, the mean score obtained is less than 80% of the total items evaluated, and may establish the idea of low adherence to good practices in the execution of insulin therapy care, consequently, the poor agreement of patients to the guidelines in insulin therapy performed by nurses. In addition, the same study showed a higher percentage of time in hyperglycemia in the period of self-administration of insulin, when compared with the period in which insulin was administered by nurses. Also, the analysis of the relationship between the scores of the insulin injection technique with the mean amplitude of the glycemic excursion (MAGE) ($P < 0.05$) and the level of HbA1c ($P < 0.05$) showed a statistically significant negative correlation, indicating that the lower score of the insulin therapy technique correlates with higher GV[18].

Despite the effectiveness of the exogenous insulin hormone, it is an injectable medication sensitive to external environmental factors that can culminate in changes in its potency and effectiveness. Thus, storage in inappropriate environments with extreme temperatures, failures in the art related to precise aspiration, needle insertion angulation in the subcutaneous (SC), formation of the subcutaneous fold,

application in recommended locations, rotation of application and reuse of needles; as well as gaps in post-application final care such as massaging the application sites, immediate removal of the SC needle and disposal of sharps in inappropriate locations can compromise the overall quality of insulin, resulting in therapeutic failures with varied metabolic consequences and increased costs of therapy[15,19].

At this juncture, the adherence of diabetic patients to the recommendations of good practices in the self-administration of insulin is essential for better therapeutic efficacy, since precarious knowledge added to inadequate skills, attitudes and practices in relation to the insulin therapy technique, which do not comply with guideline recommendations, create barriers to follow safe techniques for handling and administering insulin, hindering the therapeutic management of DM. These recommendations are seen as instruments that enhance favorable clinical outcomes with fewer diabetic complications and mitigate possible unnecessary and potentially serious damage resulting from poor insulin handling practices[15].

In the sphere of self-care management, diabetes education provided at the various levels of health care by multidisciplinary teams is indispensable to train the individual with diabetes, and in the more delimited scope of this process, insulin therapy education is preferably exercised by the professional nurses. Thus, the insulin injection technique should be implemented as part of diabetes education, individually in nursing and/or group consultations in the multiprofessional modality, guiding patients on the care with the practice of insulin and the benefits of good adherence to these practices before starting insulin treatment and carrying out longitudinal follow-up with reviews and evaluations of the practice of insulin therapy through the application of protocols and reminders that analyze the follow-up of recommendations in good practices of each stage of the insulin process.

In this study, the findings related to sociodemographic characterization corroborate other investigations of clinical and epidemiological nature about DM, carried out in the context of outpatient health care for people with diabetes, carried out in the states of Ceará and Rio de Janeiro, Brazil[3,20-21].

Regarding the behavior related to lifestyle habits, more than half of the diabetic population studied is characterized as sedentary, with a predominance of following a healthy diet and denying the practice of alcoholism and smoking. In addition, the descriptive analysis revealed a significant portion as a former smoker and former alcoholic, a phenomenon that can be elucidated through adherence to lifestyle modification (LSM), supported by the measures of protocols and guidelines that recommend smoking cessation and alcoholism as a priority in the secondary prevention of unfavorable clinical outcomes in the course of metabolic diseases, considering that such habits are risk factors for micro and macrovascular diabetic complications; as well as are associated with inadequate glycemic control[22].

The prevalence of females documented in this study is related not only to the sociocultural mechanisms that explain the frequent process of feminization of access to health services, but also to the increase in the prevalence of DM among women, as identified in the study with data from the National Health Survey (NHS) 2019 edition, carried out by the Brazilian Institute of Geography and Statistics (IBGE) in partnership with the Brazilian Ministry of Health (MH), in which there was a higher prevalence of self-reported diabetes diagnosis associated with females (8.4%; 95% CI: 8.0%-8.8%)[22].

Regarding formal education, it was highlighted that most of the sample had a low level of education: this finding correlates with a higher prevalence of DM (12.9%; 95% CI: 12.3%-13.5%), allowing us to infer about the protective effect of the high level of education in preventing the disease and/or complications resulting from untreated DM through greater access to information and health care, as well as a better understanding of its health problem and

the risks of poor control associated with failures to adhere to good practices in carrying out the activities proposed in the diabetes care plan[22].

It is notorious that the lower educational level is configured as a social determinant of the health-disease process, being a factor of direct interference in the follow-up of self-care activities in diabetes, since the lower the educational level of patients, the greater the difficulties in understanding the therapeutic recommendations given by health professionals, whether related to adherence failures, or related to the practice of procedures such as insulin therapy[23].

Regarding the clinical-therapeutic analysis, the majority had type 2 DM, with a disease time frame greater than a decade, presenting concomitant comorbidities SAH and DLP. Among the diabetic complications, neuropathy followed by retinopathy stands out. OAD, statins and AH are the main oral medication classes in use, which is understood by the observed phenomenon of the main comorbidities found; while in the injectable treatment route, a higher frequency of human insulins was evidenced. Findings compatible with this temporality of the disease, type of DM, morbidities, associated complications and treatment implemented were evidenced in other studies developed in a reference endocrinology outpatient clinic in DM care in Ceará and Rio de Janeiro, Brazil[3,20-21].

The literature shows the influence of education ($P < 0.001$) and the duration of diabetes ($P = 0.036$) on the level of practice of patients for techniques of handling, storage, preparation and application of insulin, elucidated in the relationship of the longer the disease, the greater the involvement with the chronic condition, which can elicit self-care in insulin therapy through practical experience, as well as patients with good educational level are more likely to understand and carry out the recommendations of good insulin practices[15].

The present study has some general limitations, in addition to the little or no published research on the object of investigation studied in the context of adherence to nursing recommendations on care with handling and conservation of insulins and on good practices in insulin therapy, such as small sample size that can make it difficult to generalize the findings to the larger population of diabetic patients assisted at the endocrinology outpatient clinic and less association with a significant P value. Moreover, because this is a cross-sectional study, no cause-effect relationship can be established between the study variables. However, the presence of such limitations did not preclude the development of the proposed study, and the objectives were successfully answered.

CONCLUSION

The analysis of the association between variables allowed us to conclude that there is a statistically significant relationship between the level of adherence to good practices in insulin therapy and glycemic control; patients categorized as not adhering to the professional recommendations on adequate self-care in insulin therapy showed lack of glycemic control, evidenced by glycemic control evaluation metrics outside the recommended targets, such as estimated TIR below 70% and SD above 50 mg/dl. Therefore, it is possible to deduce that education and improvement of the injection technique in insulin therapy are necessary to improve glycemic control.

These findings reaffirm the relevance of insulin therapy education to optimize general insulin therapy care, such as handling and storing insulin, as well as ensuring adequate practice in the correct insulin injection technique, through the recall of compliance with the stages of the insulin process, practical demonstration and training of patients and regular evaluation of their practical performance during nursing appointments. This study can be useful as a support for the development of other research in the evaluative field of patients' adherence/compliance with the recommendations of diabetologist nurses on good practices in performing self-care activities in insulin therapy and its relationship with glycemic control.

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Responsible editors:
Patrícia Pinto Braga – Editor-in-Chief
Daniel Nogueira Cortez – Scientific Editor

Note: This research is the result of the Residency Conclusion Work (RCW), presented to the Uniprofessional and Multiprofessional Integrated Residency Program in Hospital Health Care, area of concentration – specialization in diabetes care, of the Walter Cantídio University Hospital (WCUH). There was no funding from a funding agency.

Received: 09/02/2023
Approved: 14/06/2023

How to cite this article:
Silva MAA, Moreira TR, Negreiros FDS, Araújo ST, Donato IM. Adherence to good practice recommendations in insulin therapy: relationship with glycemic control. Revista de Enfermagem do Centro-Oeste Mineiro. 2023;13:e4993. doi: 10.19175/recom.v13i0.4993