BJPS

Brazilian Journal of
Pharmaceutical Sciences

http://dx.doi.org/10.1590/s2175-97902023e23264

Article

Pharmacotherapeutic follow-up in patients with type 1 diabetes in context of judicialization: possibility optimize costs

William Neves Oliveira[1], Maurílio Souza Cazarim[2], Thays Santos Mendonça[3], Paulo Roque Obreli-Neto[4], Mariana Linhares Pereira[5], André Oliveira Baldoni[5*]

[1]Health Sciences, Federal University of São João del-Rei (UFSJ), Divinópolis-MG, Brazil, [2]Department of Pharmaceutical Sciences, Faculty of Pharmacy, Federal University of Juiz (UFJF) de Fora, Juiz de Fora-MG, Brazil, [3]Sciences da Saúde, Federal University of São João del-Rei (UFSJ), Divinópolis-MG, Brazil, [4]Pharmacy Department, University Center of Integrated Colleges of Ourinhos, Ourinhos-SP, Brazil, [5]Pharmacy Course of the Federal University of São João del- Rei (UFSJ), Divinópolis-MG, Brazil

In Brazil, insulin analogs stand out as one of the most demanded medications by judicial means. However, the guarantee of judicial access does not guarantee rational use. In context, pharmacotherapeutic follow-up (PF) is shown to be clinical effective strategy for patients with diabetes. To evaluate direct medical costs one year after performing PF in patients with type 1 diabetes mellitus using insulin analogs ordered by court in Public Health System (Sistema Único de Saúde - SUS). This is a partial economic analysis, nested within a quasi-experimental study. Patients with T1DM who receive insulin analogs by judicialization in a medium-sized Brazilian city participated. The PF was conducted following the method adapted from the Pharmacotherapy workup (PW). Data were collected considering the period of one year before the start of the intervention and one year after the start of the intervention. Direct medical costs were evaluated and the difference in costs was calculated. 28 patients participated in the intervention. After PF, direct costs were -$3,696.78. Sensitivity analysis showed that there is a 33.4 % chance for PF to present cost savings when compared to baseline. The PF has the potential to reduce direct medical costs from the perspective of the SUS.

Keywords: Pharmaceutical care. Health's judicialization. Economic analysis. Diabetes Mellitus. Insulin analogs.

INTRODUCTION

The world prevalence of diabetes mellitus (DM) is 9,8 % and Brazil ranks six in the world prevalence ranking (International Diabetes Federation [IDF], 2021). In country, it is estimated that 5 to 10% of all DM cases are T1DM (Brazilian Society of Diabetes, 2022). Although there is a lower prevalence of Type 1 diabetes mellitus (T1DM) when compared to type 2 diabetes mellitus (DM2), the incidence of T1DM still increases by about 3 % per year (IDF, 2021). Once the diagnosis of T1DM is established, treatment with insulin replacement is essential, since the disease is characterized by insufficient production of this hormone (American Diabetes Association, 2023).

In recent years, with the expansion of pharmacists in health teams around the world, important contributions to individuals with diabetes mellitus (DM) have been shown (Hui *et al.*, 2022; Khan *et al.*, 2022), especially in relation to glycemic control and reduction in the progression of disease complications (Aquino *et al.*, 2019; Jeong, Lee, Ji, 2018; Rivera *et al.*, 2021). The care provided by these professionals to the patient and to society is consolidated in the provision of pharmaceutical services, such as pharmacotherapeutic follow-up (PF). In this service, the

***Correspondence:** A. O. Baldoni. Núcleo de Ensino e Pesquisa em Farmácia Clínica (NEPeFaC). Universidade Federal de São João Del-Rei (UFSJ). Rua Sebastião Gonçalves Coelho, 400. CEP:35501-296 – Bairro Chanadour, Divinópolis, MG, Brasil. Phone: +55 (37) 3221-1164. E-mail: andrebaldoni@ufsj.edu.br. ORCID: https://orcid.org/0000-0001-6379-0415

pharmacist, through meetings with patients, seeks to prevent, identify, and solve pharmacotherapeutic problems (PP), becoming responsible for monitoring them during their treatment with medication (Hepler, Strand, 1990).

In addition to the clinical benefits, PF brings favorable economic outcomes, since it can reduce direct medical costs, such as hospitalizations, number of medications used, medical consultations, and urgent and emergency consultations (Desse *et al.*, 2021; Jackson *et al.*, 2019; Obreli-Neto *et al.*, 2015). Therefore, the American Diabetes Association (ADA, 2023) suggests the incorporation of this professional in the approach of the patient with DM. Accordingly, in Brazil, the Ministry of Health recently published Ordinance Nº. 635/2023, which institutes, defines, and creates federal financial incentives for the implementation, costing, and performance of multidisciplinary teams in Primary Health Care. With this new regulation, clinical pharmacists can be included in the multidisciplinary team, aiming at a more complete treatment and with better clinical and economic results and better quality of life for patients, especially those with diabetes mellitus (Brazil, 2023).

Although there are several studies that show PF outcomes, it should be noted that the context in which they are carried out does not selectively include patients with T1DM and using insulin analogs acquired through the judicial system. These medications have a high cost, and therefore are often the target of lawsuits by patients with DM who wish to acquire them through the Public Health System (*Sistema Único de Saúde* - SUS) (Oliveira *et al.*, 2021; Pinheiro *et al.*, 2019).

The frequent judicialization of these high-cost analogues was a predominant factor in their incorporation in the treatment of Type 1 Diabetes Mellitus by the SUS. However, even after the incorporation of rapid-acting and long-acting insulin analogues in the SUS, which occurred in 2016 and 2019, respectively, cases of judicialization continue to occur. This is because access to these medications by the SUS is subject to the inclusion criteria established in the Clinical Protocols and Therapeutic Guidelines (PCDT) of the Ministry of Health, which are often not met by some patients. Routinely, the judiciary takes into account only the opinion of the prescriber, without considering the PCDT (Brazil, 2017; Brazil, 2019).

This process of judicialization of health comprises court decisions that force the government to provide medications and health services based on the right to health, as defined by the Federal Constitution of 1988 (Chieffi, Barradas, Golbaum, 2017). However, compliance with these court orders has a significant effect on public health management in the country, which is naturally hampered by unscheduled expenditures (Machado *et al.*, 2011), in addition to making the system less fair and rational (Wang, 2013).

Studies carried out in different states in Brazil have shown that insulins glargine and aspart led the judicial requests (Chieffi, Barradas, Golbaum, 2017; Oliveira *et al.*, 2021; Santos *et al.*, 2018). Thus, investigations in this population group are necessary, since the existing gaps in this theme make it difficult to implement strategies that rationalize health resources in line with the optimization of care for these patients.

In this sense, this study aimed to evaluate the direct medical costs before and after PF of patients with T1DM using insulin analogs obtained through the courts.

METHODS

Design, Population and Local of Study

The present work is a quasi-experimental single-arm study with analysis of direct medical costs of patients with T1DM, who receive insulin analogs via judicialization in a medium-sized Brazilian municipality. The municipality is located in the state of Minas Gerais and has an estimated population of 238,230 inhabitants.

Pharmacotherapeutic Follow-up (PF)

The PF consisted of five consultations (steps) with the clinical pharmacist, with the objective of 1 - To perform laboratory tests (fasting blood glucose, glycated hemoglobin, triglycerides, total cholesterol and fractions); Collect sociodemographic, clinical and therapeutic data and analyze knowledge about insulin analogs and their application techniques. 2 - Conduct general discussions about DM, empower patients for self-care, discuss ways to prevent acute and chronic

complications and establish therapeutic goals. 3 - Evaluate the interventions performed and discuss with patients about lifestyle changes in the treatment of DM. 4 - Review the topics covered in the previous steps and identify possible doubts regarding the control of DM; Schedule new laboratory tests. 5 - Evaluate results of laboratory tests; Carry out new collection of clinical and therapeutic data and present the results obtained to the patients The PF was conducted following the method adapted from the pharmacotherapy workup (PW) (Morley, Strand, Cipolle, 2004). Each consultation lasted from 20 to 40 minutes.

The evaluation of the clinical and humanistic results of PF was also performed by Mendonça *et al.* (2022).

Selection of patients

Patients who received insulin analogs for the treatment of T1DM through lawsuits in a medium-sized municipality in the State of Minas Gerais, Brazil, in 2019, corresponded to the target population of the present study. In the recruitment stage, the pharmacy responsible for the supply of medications through the judicial process made available a record of the dispensing of analogs with patients using these medications, and thus, potentially eligible patients were identified.

The following were included in the study: patients with T1DM, of both genders, using insulin analogs received through the courts in the municipality where the study took place. Patients unable to attend the pharmacy for pharmaceutical consultations, such as bedridden patients, were excluded from this study. In 2019 there were 93 patients with T1DM who received insulin analogs by court decision. The invitation to participate in the study was carried out with 100 % of the patients. Thus, the intervention was performed only with patients who agreed to participate. Figure 01 presents the recruitment process of study participants.

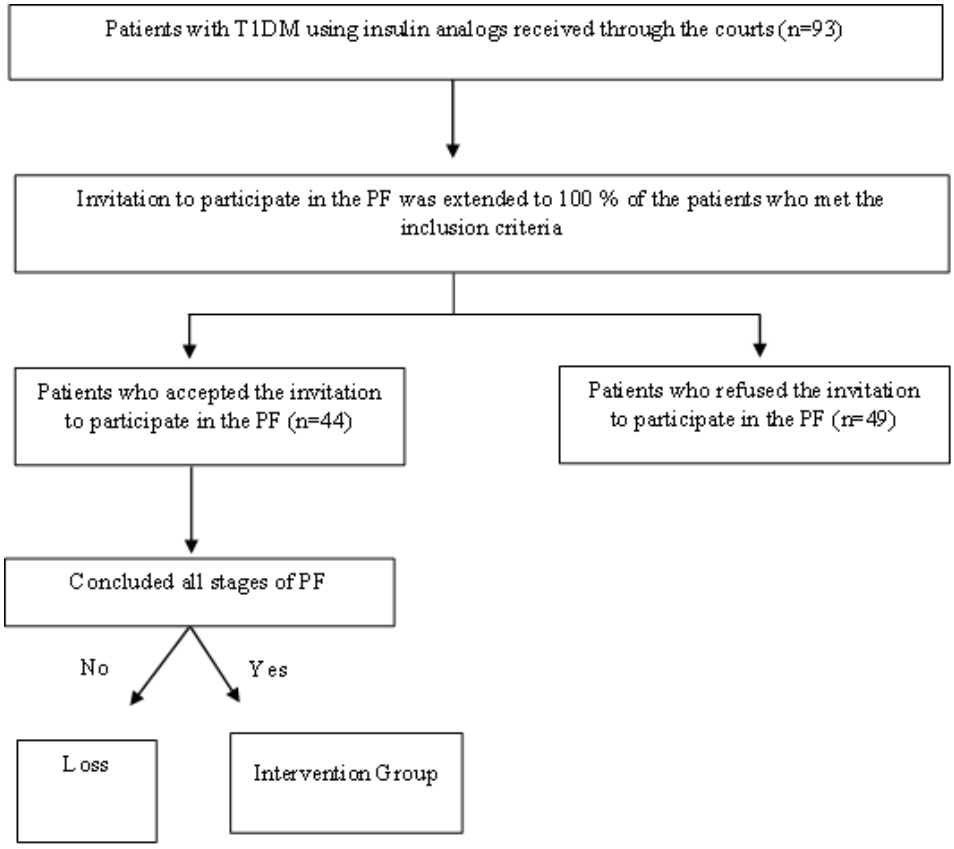

FIGURE 01 - Study participant recruitment process.

Legend: T1DM- Diabetes Mellitus type 1; PF- Pharmacotherapeutic Follow-up

The selection of patients was based on criteria established by the checklist of the Reporting of intervention evaluation studies using non-randomized designs (Des Jarlais, Lyles, Crepaz, 2004). Due to the high number of refusals, patients were not randomized into groups and data collected at the end of the experimental phase was compared with historical control of the same patients (before and after). The results of the quasi-experimental study were analyzed in terms of direct costs regarding the effect of treatment in T1DM with insulin analog required through the courts from the perspective of the SUS. The study took place from April 2019 to August 2020.

Data collection and source

Data were collected considering the period of one year before the start of the intervention (baseline) and one year after the start of the intervention (follow-up). These data were collected using electronic medical records, authorization for hospital admission, and a questionnaire used during PF. Gender, age, time since diagnosis of T1DM, and time since judicialization, were collected.

Identification and measurement of costs

The variables used to measure the direct medical costs of each patient were:

1. Medications acquired from the SUS (insulin analogs, auxiliary supplies in the treatment of DM, medication for non-communicable chronic diseases and other medication);
2. Medical consultations at the primary healthcare units;
3. Consultations in secondary care (ophthalmology, cardiology, endocrinology, angiology, and nephrology);
4. Nursing consultations;
5. Urgent and emergency care, and;
6. Hospital admission.

To assess direct medical costs before and after PF, the absolute number of resources consumed by each patient was multiplied by their cost (defined by different methods). Table I presents the process of identification, measurement and source of cost collection.

TABLE I – Identification, measurement and source of cost collection

Costs	Measurement of costs	Source of cost collection
Medication: Insulin analogs NCDS (Chronic Non-Communicable Diseases) Others	Absolute number of resources consumed by each patient X the cost of the medication	CMED medication price list, reference September/2021.
Inputs for the treatment of type 1 diabetes mellitus: Lancets for finger puncture Needles Syringes Test strips for glucometer	Absolute number of resources consumed by each patient X the cost of the input	Price paid by the Municipal Health Department (SEMUSA), reference September/2021.
General and urgent/emergency medical consultations at primary healthcare units	Absolute number of consultations consumed by each patient X consultation cost	Salary floor of a Family Health Strategy (FHS) physician in the municipality[1]
Nursing consultations at primary healthcare units	Absolute number of consultations consumed by each patient X consultation cost	Salary floor of an FHS nurse in the municipality[1]

TABLE I – Identification, measurement and source of cost collection

Costs	Measurement of costs	Source of cost collection
Consultations with a specialist doctor	Absolute number of consultations consumed by each patient X consultation cost	SIGTAP table base/year 2021
Urgent and emergency consultations in emergency care units	Absolute number of consultations consumed by each patient X consultation cost	SIGTAP table base/year 2021
Hospital admissions	Resources consumed during the hospitalization period	Authorization for Hospital Admission (AHA)
PF [2]	Absolute number of consultations consumed by each patient X consultation cost	Salary floor of an FHS pharmacist in the municipality[1]

[1]An average service time of 30 minutes was considered. [2]Costs calculated for the intervention period only. SIGTAP: Management System for the Table of Procedures, Medications, Orthoses/Prostheses and Special Materials of the Unified Health System. SUS: Public Health System. CMED: Medications Market Regulation Chamber. NCDS: Chronic non-communicable disease; PF: Pharmacotherapeutic follow-up. SEMUSA: Municipal Secretary of Health

Analysis of costs

The time horizon defined for the analysis was one year. The costs were adjusted for the year 2022, when previous values were collected. For this, the adjustment was carried out by the National Consumer Price Index (*Índice Nacional de Preços ao Consumidor* - INPC), available in the consolidated economic indicators of the Central Bank of Brazil, with the calculation performed as follows: cost x (1+[[INPC (year of cost)) x…(1+[[INPC]]_ (year 2022)) (Rascati, 2010).

Data analysis

A descriptive analysis of direct medical costs was performed. For the intervention period, the cost of PF was added to the analysis. Direct cost analysis was measured by the difference in costs obtained from subtraction (Intervention costs – Baseline costs) and the difference in costs per patient was performed from the difference in costs divided by the number of participants. The characteristics of the study participants were described. Continuous variables are shown as mean and standard deviation. All analyses were performed using Microsoft Excel 2016 software.

Sensitivity analysis

Monte Carlo analysis was performed using @ Risk software version 8.2 of 2021 from Palisade Corporation®. The significance level of the analyses was 5 % for the probability density curve for summary and dispersion measures and for the Tornado diagram. The Tornado diagram measured the influence of cost variables according to cost variance for the direct analysis summary measure, the cost difference between PF and baseline.

The Anderson-Darling statistic was used to test the fit of the data set to a specific distribution probability, the better the distribution fits the data, the lower this statistic and the higher the p-value. The significance level for adequacy to the probability curve distribution was 1 %.

Ethical considerations

The study was developed in accordance with the guidelines and regulatory standards for research involving human beings, approved by the Research Ethics Committee of the Federal University of São João del-Rei (UFSJ), under opinion number 2,760,677.

RESULTS

Of the 93 patients who received insulin analogs judicially in 2019, 44 (47.3 %) agreed to participate in the PF. Among those who agreed to participate, 28 (63.6 %) completed all stages of the study. The mean age was 32.3 years and females were more frequent (53.6 %). The mean time since diabetes diagnosis was 18.9 years and duration of judicialization was 9.2 years. In the analysis of medication already used for the treatment of T1DM before judicialization, it was observed that 10 (38 %) patients had no records of previous use of insulin. With regard to judicialized medication, the ultra-fast insulin analog aspart was the most widely used (89.3%), followed by the ultra-slow insulin analog glargine (71.4%). There were also 23 patients (82.1%) who acquired two types of insulin through judicialization.

After PF, the total difference in Total ultra-fast insulins analogs costs was +$220.81 and Total ultra-slow insulins analogs was -$3,765.28. The total difference in direct medical costs was -$3,696.78 and the difference per patient was -$132.03 (Table II). There was no hospitalization for T1DM or its complications during the period evaluated and therefore this result was not presented.

Sensitivity analysis showed that there is a 33.4 % chance (5 % confidence) that the PF will present cost savings ($0 to - $136.37 per patient) when compared to the baseline (without PF). In addition, it is observed that the difference in costs between PF and baseline had minimum, average, and maximum values of -$466.23, $26.82 and $495.76, respectively. The PF (compared to the baseline) could generate a maximum cost saving of $466.23 or, in a worst-case scenario, a maximum increase in costs of $495.76. (Figure 02).

TABLE II – Direct medical cost variables before and after PF (N=28)

Cost variables	One year before PF	One year after the start of PF	Difference
Consultations		**$ (dollar)**	
Physician (general practitioner) in primary healthcare units	158.04	94.82	-63,22
Nursing in primary healthcare units	2.89	0	-2.89
Urgent and emergency physicians in primary healthcare units	18.96	12.64	-6.32
Physicians in specialized care	49.87	38.36	-11.51
Emergency doctors in emergency care units	8.44	8.44	0
Medications			
Insulin Aspart	3,913.03	4,125.69	+212.66
Insulin Lispro	380.69	317.24	-63.45
Insulin Glulisine	299.05	370.65	+71.60
Total ultra-fast insulins analogs	4,592.77	4,813.58	+220.81
Ultra-Slow insulins analogs			
Insulin Glargine	7,717.46	6,073.85	-1643.61
Insulin Degludec	2,762.64	975.05	-1787.59
Insulin Detemir	1,159.40	915.32	-244.08

TABLE II – Direct medical cost variables before and after PF (N=28)

Cost variables	One year before PF	One year after the start of PF	Difference
Consultations		**$ (dollar)**	
Total ultra-slow insulins analogs	11,639.50	7,964.22	-3,675.28
Total Ultra-Fast and Ultra-Slow Insulin analogs	16,232.27	12,777.80	-3,454.47
Inputs for the treatment of T1DM	3,263.67	2,683.49	-580.18
For NCDS	357.79	437.77	+79.98
Other medications	35.12	74.84	+39.72
PF	N/A	302.08	+302.08
Difference* intervention group	20,127.05	16,430.27	-3,696.78
Difference* per patient	718.82	586.79	-132.03 (↓18.37%)

Intervention costs - Baseline costs

PF-Pharmacotherapeutic Follow-up; NCDSs-Chronic Non-Communicable Diseases; T1DM-Type 1 Diabetes Mellitus.

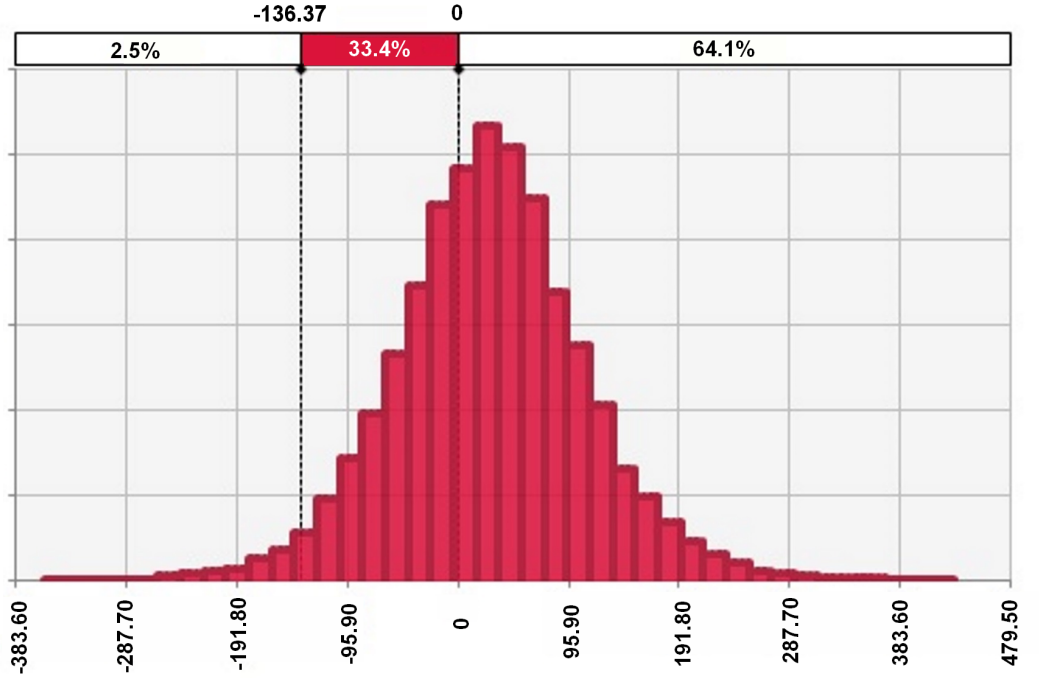

FIGURE 02 - Probability Density for the summary measures of the cost difference between PF and baseline

Legend: PF: Pharmacotherapeutic follow-up. Among the cost variables, the following distributions were defined: CNCD Medication, DM Medication, DM Supplies were suitable for the largest extreme value distribution. Other medications, Consultations with clinical physicians, Consultations with nurses, Consultations with endocrinologists, Urgent medical consultations, Urgent consultations at emergency care units were adjusted to the smallest extreme value according to the analyses.

Insulin analogs stand out for representing the greatest impact on the variation of costs between PF and baseline (-$55.14 to $153.23), followed by supplies for the treatment of T1DM ($8.22 to $57.64) and medications for NCDSs ($14.30 to $33.81) (Figure 03).

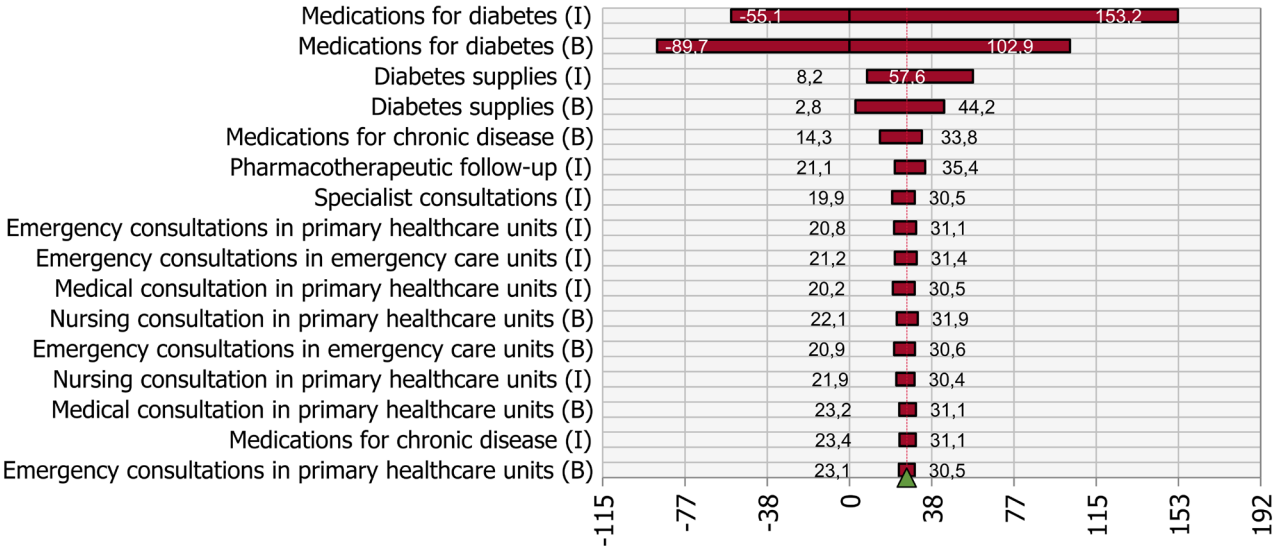

FIGURE 03 - Ranking of the influence of variables on the difference in costs between PF and baseline.
Legend: I-Intervention; B-Baseline; PF- Pharmacotherapeutic Follow-up.

DISCUSSION

This study showed that direct medical costs were reduced by $132.03 per patient (18.37 %) after the pharmaceutical intervention and that there is a 33.4 % chance that the PF will show cost savings. The literature has not shown studies that evaluate the economic results of PF specifically on patients with T1DM and using legally required medications. However, there are mostly international publications that present economic results of pharmaceutical interventions in other populations, such as patients with chronic diseases (Desse *et al.*, 2021; Schultz *et al.*, 2021).

A Brazilian study showed that the implementation of a pharmacotherapeutic empowerment strategy for patients with type 2 DM promoted glycemic control at a lower cost when compared to traditional care, generating resource savings. The authors noted that a 0.359 reduction in glycated hemoglobin (A1c) costs US$708.47 in the intervention group and a 0.170 reduction costs US$1,927.13 in the control group, with an incremental cost-effectiveness ratio (ICER) of US$387.66 per patient/year (Gonçalves *et al.*, 2019). In contrast, another national study showed that PF did not significantly improve the total direct health care costs of patients with DM and systemic arterial hypertension (SAH), but significant clinical results were observed (Obreli-Neto *et al.*, 2015).

Jackson and cols. (2019) showed that healthcare costs were reduced from US$5,910.76 to US$4,290.30 per patient/year by including community pharmacists in patient care in North Carolina (USA). Moore and cols. (2013) evaluated the impact of PF in 4,500 patients with chronic diseases on healthcare costs paid by private health plans in the US. The intervention reduced expenditures by US$1,201.59. Another study carried out in the USA with 2,480 patients with a mean age of 65 years, with two or more chronic health conditions, and using four or more medications, showed that PF improved clinical parameters and reduced hospitalizations by 23.4 %, generating an

estimated saving of US$ 2,778.50 per patient. The return on investment was 504 % (Matzke *et al.*, 2018).

In Canada, a study carried out with 227 patients with a mean age of 60 years, with SAH or other cardiovascular diseases, showed that PF promoted savings in cardiovascular events of US$ 112.22/patient/year for the Canadian health system (Houle *et al.*, 2012). As mentioned, although incipient, most economic studies are developed in the US and from the perspective of private health systems. Therefore, the results of this study can provide a great opportunity to reflect on some perspectives and considerations related to the economic impact of PF in a scenario of judicialization and especially in a national public health system.

Firstly, it is important to note that the effectiveness of analogue insulins in relation to conventional insulins is not yet fully established, since studies have shown conflicting results (Hasan *et al.*, 2023; Mannucci *et al.*, 2021; Semlitsch *et al.*, 2020). Despite this lack of consensus, rapid and long-acting insulin analogues were incorporated into the SUS in 2017 and 2019, respectively (BRAZIL, 2017; BRAZIL, 2019). The pressure exerted by frequent judicialization is a factor that drives the need to incorporate new health technologies (Vasconcelos *et al.*, 2017). However, access to analogues is subject to criteria established by the Ministry of Health, through clinical protocols that, in many cases, are not met by some patients. This leads to a search by the justice system, as an attempt to legally circumvent these established criteria. Despite the inclusion of analogues in the SUS, there are still no studies available that demonstrate the scenario and profile of lawsuits related to these post-incorporation drugs.

Firstly, it should be noted that the superior effectiveness of insulin analogs in relation to conventional insulins is not yet well established. Studies have shown conflicting results (Hasan *et al.*, 2023; Mannucci *et al.*, 2021; Semlitsch *et al.*, 2020). In addition, conventional insulins (NPH and regular) are available in the public health system. In other words, filing lawsuits, especially in this context, should be avoided, since there is a therapeutic alternative available and, above all, offered by the public health system.

Secondly, it is necessary to consider that the supply of medication through legal disputes does not necessarily constitute an effective guarantee of the right to health, and let alone quality clinical care. Although a judicial decision is favorable to the citizen, this does not always result in benefits for the individual (Travassos *et al.*, 2013) and with regard to medication, their irrational use and their use without monitoring can generate, in addition to health consequences, social costs, especially direct costs with treatments and hospitalizations, as well as indirect costs arising from absence from work, disability and death (Figueiredo, Pepe, Osorio-de-Castro, 2010). It is observed that many patients resort to lawsuits as a way to circumvent the stages of the healthcare system, using the SUS only to obtain free medication. It is important to emphasize that these drugs are often prescribed by private healthcare professionals who are responsible for patient care. By using the SUS only as a "gateway" to obtain medication, these individuals compromise the quality and continuity of their medical care (Machado *et al.*, 2011; Mendonça *et al.*, 2023). This situation reinforces the need for a more comprehensive and integrated approach in the healthcare system, promoting greater coordination among the different levels of care.

After a court order to supply the medication, the Judiciary does not have a form of official follow-up that monitors the conditions of use, the patient's evolution, or the achievement of the therapeutic goals aimed by the prescriber. In other words, the supply of medications through this route is only one of the steps, whereas others are necessary for the treatment to be truly effective (Figueiredo, Pepe, Osorio-de-Castro, 2010). Sant'Ana and cols. (2011) concluded in their work that the judge could suggest a follow-up of the patient, with the objective of guaranteeing effective access to health and justice, promoting the rational use of medications and avoiding possible fraud or misapplication of public resources. It was in this sense that the study by Mendonça and cols. (2022) explained that PF brought clinical and humanistic benefits, with an improvement in the quality of life and health of patients who use insulin analogs through judicialization.

The economic impact that the acquisition of insulin analogs causes on the municipality (in which this study was conducted) could be mitigated by the incorporation of PF given that, after the implementation of PF, there is mainly a decrease in expenses with medications

and supplies for treatment of DM, as evidenced in the sensitivity analysis. Corroborating this finding, a study showed that after pharmaceutical intervention, medication costs were reduced from US$ 1,219.72/patient/year to US$ 858.57/patient/year (Jackson *et al.*, 2019). It is important to highlight that during the PF, failures were identified in the pharmacotherapy of some patients, such as untreated health conditions, which generated referrals to the physician, which may have driven the significant increase in the amount of medications used by these patients (Mendonça *et al.*, 2022), so this may explain the present study finding an increase in the costs of medications for NCDSs.

It is necessary to consider that DM is proven to be associated with long-term complications that lead to high morbidity and mortality, and with this there is a worsening in quality of life and increased health costs (Papatheodorou *et al.*, 2018; Simeone *et al.*, 2020). Some diseases and clinical conditions may require longer periods for more complex clinical outcomes to manifest (2010, 2012). Against this background, there is a scarcity of studies that prevents us from measuring the dimension of the long-term impact generated by PF on direct medical costs.

Thus, efforts need to be made to carry out economic evaluations considering analytical horizons long enough to reflect the main differences in health costs. In our study, we believe that the results could have been more expressive if the PF had occurred for a less limited duration, since our patients are relatively young (age group of 30 years), and therefore, the complications of the disease are less likely, which can be evidenced by the absence of hospitalizations in the studied period.

It is noteworthy that our article is innovative in studying a population group that at first has not yet been explored. However, some limitations need to be presented: 1) The composition of the costs occurred only from the municipal point of view. However, this limitation may not be so important, since it is a real-world study, where the participants actually judicialized insulin analogs and the costs were actually borne by the municipal perspective. 2) Data collection for most variables occurred through self-report, which may have contributed to an information bias, and consequently, an underestimation of costs. 3) The study did not consider the factor of value sequestration, which is common in lawsuits. When values are sequestered, the amount to be paid generally follows the Maximum Consumer Price (PMC), which is higher than the Factory Price (PMVG) used in the study. The study used the cost calculated under the PMVG as a default value for all patients followed up after the end of pharmacotherapeutic follow-up. However, if the analysis had considered each individual process, the results could be more favorable to pharmacotherapeutic follow-up, due to the potentially higher cost (PMC) than that used in the study (PMVG). 4) The number of participants was reduced due to patients' refusal and loss of follow-up, which can lead to a selection bias, with the profile of participants being different from those who did not accept to participate or who dropped out of the study. 5) During data collection, we encountered difficulties in measuring the costs of consultations with nutritionists and psychologists due to the existence of two health information systems in the municipality. Each professional, depending on the healthcare facility they worked in, recorded the information in a different system. Unfortunately, due to the integration of these systems during the period of our study, some specific information from these professionals was lost, making it impossible to include these costs in our analysis. It is important to emphasize, however, that this limitation does not diminish the essential importance of these professionals in the clinical context and comprehensive care of patients with DM.

Finally, the pharmacoeconomic analysis process is still a recent reality, the absence of systematization of these routines can make it difficult to clearly identify the best decision to be taken. However, even in the case of a partial economic analysis, the present study represents a possibility of advancement in this issue of implementation of PF in patients using medication by the judicial system. In addition, our results may drive future pharmacoeconomic studies that have answers to other questions for the judicialization of patients with DM, in addition to being a guideline for the cost of other studies, such as those of cost-effectiveness.

CONCLUSION

The results suggest that PF may be able to reduce direct medical costs from a perspective of the municipal

public health service, of patients with T1DM in use of medication requested through the courts. Despite our limitations, this study represents an awakening to the fact that inserting pharmacists into DM patients' healthcare process can optimize the use of resources that would otherwise be spent as a result of judicialization.

CONFLICTS OF INTEREST:

The authors declare that there are no conflicts of interest.

SOURCES OF FUNDING:

This work was supported by the Brazilian National Council for Scientific and Technological Development (CNPQ)–Process: 405145/2018–7 and by the Coordination for the Improvement of Higher Education Personnel–Brazil (CAPES) – Finance code 001.

REFERENCES

American Diabetes Association.(ADA). Diabetes Care. 2023;46(Supplement_1):S10-18. https://doi.org/10.2337/dc23-S001

Aquino JA, Baldoni AO, Di Lorenzo Oliveira C, Cardoso CS, de Figueiredo RC, Sanches C. Pharmacotherapeutic empowerment and its effectiveness in glycemic control in patients with Diabetes Mellitus. Diabetes Metab Syndr Clin Res Rev.2019;13(1):137-42. https://doi.org/10.1016/j.dsx.2018.08.002.

Brazil. Ministry of Health. Ordinance Nº. 10, of February 21, 2017. Makes public the decision to incorporate fast-acting insulin analogues for the treatment of type I diabetes mellitus, within the scope of the Unified Health System. Diário Oficial da União, Brasilia: Ministry of Health, 2017. In Portuguese.

Brazil. Ministry of Health. Ordinance Nº. 19, of March 27, 2019. Establishes, defines and creates federal financial incentives for the implementation, costing and performance of multidisciplinary teams in Primary Health Care.. Diário Oficial da União, Brasilia: Ministry of Health, 2019. In Portuguese.

Brazil. Ministry of Health. Ordinance Nº. 635, of May 22, 2023. Makes public the decision to incorporate long-acting insulin analogues for the treatment of type I diabetes mellitus, within the scope of the Unified Health System. Diário Oficial da União, Brasilia: Ministry of Health, 2023. In Portuguese.

Brazilian Society of Diabetes. Guidelines of the Brazilian Society of Diabetes (SBD): 2022–2023. Brazilian Society of Diabetes; São Paulo, Brazil: 2023.

Chieffi AL, Barradas RDCB, Golbaum M. Legal access to medications: A threat to Brazil's public health system? BMC Health Serv Res. 2017;17(1):499. https://doi.org/10.1186/s12913-017-2430-x.

Des Jarlais DC, Lyles C, Crepaz N. Improving the Reporting Quality of Nonrandomized Evaluations of Behavioral and Public Health Interventions: The TREND Statement. Am J Public Health. 2004;94(3):361-6. https://doi.org/10.2105/AJPH.94.3.361.

Desse TA, Vakil K, Namara KM, Manias E. Impact of clinical pharmacy interventions on health and economic outcomes in type 2 diabetes: A systematic review and meta-analysis. Diabet Med. 2021;38(6):e14526. https://doi.org/10.1111/DME.14526.

Figueiredo TA, Pepe VLE, Osorio-de-Castro CGS. A sanitary focus on medicines lawsuit. Physis. 2010;20(1):101-18. https://doi.org/10.1590/s0103-73312010000100007.

Gonçalves ACO, Cazarim MDS, Sanches C, Pereira LRL, Camargos AMT, Aquino JA, et al. Cost-effectiveness analysis of a pharmacotherapeutic empowerment strategy for patients with type 2 diabetes mellitus. BMJ Open Diabetes Res Care. 2019;7(1):e000647. https://doi.org/10.1136/bmjdrc-2018-000647.

Hasan M, Atiqur-Rahman M, Chowdhury S, Esteak T, Naznin J, Shahi MS. Efficacy and Safety of Analog Insulin in Comparison With Human Insulin for Hyperglycemia in Hospitalized Patients With Acute Stroke: A Randomized, Open-Label, Single-Center Trial. Endocr Pract. 2023;29(1):18-23. https://doi.org/10.1016/j.eprac.2022.10.180.

Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990;47(3):533-43. https://doi.org/10.1093/ajhp/47.3.533.

Houle SKD, Chuck AW, McAlister FA, Tsuyuki RT. Effect of a pharmacist-managed hypertension program on health system costs: An evaluation of the study of cardiovascular risk intervention by pharmacists-hypertension (SCRIP-HTN). Pharmacotherapy. 2012;32(6):527-37. https://doi.org/10.1002/j.1875-9114.2012.01097.x.

Hui X, Yinghua Z, Shengxiong X, Qingfa Z, Yingjun G. The effectiveness of daily humanistic care in pharmaceutical care of patients with type 2 diabetes. Med (United States). 2022;101(41):E30136. https://doi.org/10.1097/MD.0000000000030136.

International Diabetes Federation [IDF]. IDF Diabetes Atlas. 10th ed. 2021.

Jackson DL, Michaels NM, Melson B, Bruder E, Rhodes LA, Marciniak MW. Evaluation of the economic and clinical impact of community pharmacist-driven pharmacy benefit management services. J Am Pharm Assoc. 2019;59(4):S91-4. https://doi.org/10.1016/j.japh.2019.03.016.

Jeong S, Lee M, Ji E. Effect of pharmaceutical care interventions on glycemic control in patients with diabetes: a systematic review and meta-analysis. Ther Clin Risk Manag. 2018; 14:1813-29. https://doi.org/10.2147/TCRM.S169748.

Khan YH, Alzarea AI, Alotaibi NH, Alatawi AD, Khokhar A, Alanazi AS, et al. Evaluation of Impact of a Pharmacist-Led Educational Campaign on Disease Knowledge, Practices and Medication Adherence for Type-2 Diabetic Patients: A Prospective Pre- and Post-Analysis. Int J Environ Res Public Health. 2022;19(16):10060. https://doi.org/10.3390/ijerph191610060.

Machado MA, Acurcio Fde A, Brandão CMR, Faleiros DR, Guerra AA Jr, Cherchiglia ML, et al. Judicialization of access to medicines in the State of Minas Gerais, Brazil. Rev Saude Publica. 2011;45(3):590-8. https://doi.org/10.1590/S0034-89102011005000015.

Mannucci E, Caiulo C, Naletto L, Madama G, Monami M. Efficacy and safety of different basal and prandial insulin analogues for the treatment of type 2 diabetes: a network meta-analysis of randomized controlled trials. Endocrine. 2021;74(3):508-17. https://doi.org/10.1007/s12020-021-02889-6.

Matzke GR, Moczygemba LR, Williams KJ, Czar MJ, Lee WT. Impact of a pharmacist-physician collaborative care model on patient outcomes and health services utilization. Am J Health Pharm. 2018;75(14):1039-47. https://doi.org/10.2146/ajhp170789.

Mendonça TS, Oliveira WN, Belo VS, Silva ES, Pereira ML, Obreli-Neto PR, et al. Clinical and humanistic impact of pharmacotherapeutic follow-up in patients with type 1 diabetes mellitus treated judicially. Diabetol Metab Syndr. 2022;14(1):61. https://doi.org/10.1186/s13098-022-00835-8.

Mendonça TS, Silva ES, Pereira ML, Obreli-Neto PR, Belo VS, Ferreira GC, et al. Patients in insulin analogues use via judicial litigation: do they use the Brazilian Public Health System (SUS)? Cad Saúde Coletiva. 2023;31(2):e31020102. https://doi.org/10.1590/1414-462x202331020102.

Moore JM, Shartle D, Faudskar L, Matlin OS, Brennan TA. Impact of a patient-centered pharmacy program and intervention in a high-risk group. J Manag Care Pharm. 2013;19(3):228-36. https://doi.org/10.18553/jmcp.2013.19.3.228.

Morley PC, Strand L, Cipolle R. Pharmaceutical Care Practice: The Clinician's Guide, 2004.

Obreli-Neto PR, Marusic S, Guidoni CM, Baldoni A de O, Renovato RD, Pilger D, et al. Economic evaluation of a pharmaceutical care program for elderly diabetic and hypertensive patients in primary health care: A 36-month randomized controlled clinical trial. J Manag Care Pharm. 2015;21(1):66-75. https://doi.org/10.18553/jmcp.2015.21.1.66.

Oliveira YMDC, Fonseca Braga BS, Farias AD, De Vasconcelos CM, Fernandes Ferreira MA. Judicialization of access to medicines: Analysis of lawsuits in the state of Rio Grande do Norte, Brazil. Cad Saude Publica. 2021;37(1):e00174619. https://doi.org/10.1590/0102-311X00174619.

Papatheodorou K, Banach M, Bekiari E, Rizzo M, Edmonds M. Complications of Diabetes 2017. J Diabetes Res. 2018;2018:3086167. https://doi.org/10.1155/2018/3086167.

Pinheiro P, Garcia J, Cardoso É, Luz D, Silva V. Pharmacoeconomics: expenses with insulin analogues acquired through judicialization in a municipality in the state of Pará, Brazil, in 2016. J Bras Econ Saúde. 2019;11(1):42-8. https://doi.org/10.21115/jbes.v11.n1.p42-8.

Rascati KL. Essentials of pharmacoeconomics. Philadelphia (PA): Lippincott Williams & Wilkins, 2009.

Rivera JG, Quemel Bardález GKC, Silva VM da, Costa JG da, Silva KRP da, Costa JB. Literature review: Pharmacotherapeutic follow-up provided to type 2 diabetic patients treated at community pharmacies. Res Soc Dev. 2021;10(8):e9010817150. https://doi.org/10.33448/rsd-v10i8.17150.

Sant'Ana JMB, Pepe VLE, Osorio-De-Castro CGS, Ventura M. Essentiality and pharmaceutical assistance: Considerations on access to medicines through lawsuits in Brazil. Rev Panam Salud Publica/Pan Am J Public Health. 2011;29:138–44. https://doi.org/10.1590/S1020-49892011000200010.

Santos ECB, Teixeira CRS, Zanetti ML, Istilli PT, Pereira LHTR, Torquato MTDCG. Judicialization of health: Access to treatment for users with diabetes mellitus. Texto Context Enferm. 2018;27(1):1-7. https://doi.org/10.1590/0104-070720180000800016.

Schultz BG, Tilton J, Jun J, Scott-Horton T, Quach D, Touchette DR. Cost-Effectiveness Analysis of a Pharmacist-Led Medication Therapy Management Program: Hypertension Management. Value Health. 2021;24(4):522-9. https://doi.org/10.1016/j.jval.2020.10.008.

Semlitsch T, Engler J, Siebenhofer A, Jeitler K, Berghold A, Horvath K. (Ultra-)long-acting insulin analogues versus NPH insulin (human isophane insulin) for adults with type 2 diabetes mellitus. Cochrane Database Syst Rev. 2020;11(11):CD005613. https://doi.org/10.1002/14651858.CD005613.pub4.

Simeone JC, Shah S, Ganz ML, Sullivan S, Koralova A, LeGrand J, et al. Healthcare resource utilization and cost

among patients with type 1 diabetes in the United States. J Manag Care Spec Pharm. 2020;26(11):1399-410. https://doi.org/10.18553/JMCP.2020.26.11.1399.

Travassos DV, Ferreira RC, Maria A, Vargas D, Núbia R, Moura V De, et al. The judicialization of health care: a case study of three state courts in Brazil. Cien Saude Colet. 2013;18(11):3419–3429. https://doi.org/10.1590/S1413-81232013001100031

Vasconcelos DMM, Chaves GC, Azeredo TB, da Silva RM. National Medicines Policy in retrospective: a review of (almost) 20 years of implementation. Cienc Saude Colet. 2017;22(8):2609-14. https://doi.org/10.1590/1413-81232017228.02432017.

Wang D. Courts as Healthcare Policy-Makers: The Problem, the Responses to the Problem and Problems in the Responses. SSRN Electron J. 2013. https://doi.org/10.2139/ssrn.2335145.

Received for publication on 19th April 2023
Accepted for publication on 20th July 2023