

Patients in insulin analogues use via judicial litigation: do they use the Brazilian Public Health System (SUS)?

Pacientes em uso de análogos de insulina via ação judicial: eles utilizam o Sistema Único de Saúde (SUS)?

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Abstract

Background: Studies show that among the drugs most commonly used in judicial litigation in Brazil, are those used to treat diabetes mellitus, especially insulin analogues. **Objective:** Evaluate the use of the Unified Health System (SUS) by patients with type 1 diabetes mellitus (T1DM), who receive insulin analogues through judicial action, before and after this process. **Method:** In a retrospective longitudinal observational study, secondary data was used from these patients in Minas Gerais, Brazil, in 2018. Socio-demographic information was collected and related to the follow-up of these patients in the SUS. The McNemar χ^2 test was used to compare the proportions of the variables. **Results:** Of the 89 patients analyzed, women (53.9%) were predominant. Most patients were aged between 20 and 39 years (52.8%), and more than half, 55.1%, use only a private health system. After the judicial action, there was a significant increase ($p < 0.05$) in the number of patients who had consultations in primary health care (from 19.1% to 30.3%) and emergency medical appointments (from 1.1% to 9.0%). **Conclusion:** It is observed that the majority of patients with T1DM via judicial action in the SUS are not monitored by this health system through examinations, consultations, and hospitalizations.

Keywords: diabetes mellitus type 1; insulin analogues; judicial actions; population health management; Unified Health System.

Resumo

Introdução: Estudos mostram que, dentre os medicamentos mais adquiridos via ação judicial, estão os utilizados para o tratamento do Diabetes Mellitus, especialmente os análogos de insulina. **Objetivo:** Avaliar a utilização do Sistema Único de Saúde (SUS) pelos pacientes com Diabetes Mellitus tipo 1 (DM1), que recebem insulina por meio de judicialização, antes e após este processo. **Método:** Em um estudo observacional longitudinal retrospectivo, foram utilizados dados secundários de pacientes com DM1, que adquiriram insulinas por processos judiciais em Divinópolis-MG, Brasil, em 2018. Foram coletadas informações sociodemográficas e referentes ao acompanhamento destes pacientes no SUS



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Realizou-se o teste χ^2 de McNemar para a comparação das proporções das variáveis utilizadas para a avaliação do acompanhamento antes e após a judicialização. **Resultados:** Dos 89 pacientes analisados, predominou-se o sexo feminino (53,9%), com idade entre 20 e 39 anos (52,8%). 55,1% destes utilizam apenas o sistema privado de saúde. Após a judicialização, houve um aumento significativo ($p < 0,05$) no número de pacientes que realizaram consultas na atenção primária à saúde (de 19,1% para 30,3%) e consultas médicas de emergência (de 1,1% para 9,0%). **Conclusão:** A maioria dos pacientes com DM1 que judicializam medicamentos no SUS não são acompanhados por este sistema de saúde através de realização de exames, consultas e hospitalizações.

Palavras-chave: diabetes mellitus tipo 1; insulinas; decisões judiciais; gestão em saúde; Sistema Único de Saúde.

INTRODUCTION

The implementation of the Unified Health System (SUS) in Brazil has brought a great improvement in the provision of public health services. Since 1988, in addition to counting on the private system, Brazil has had a public system that seeks to guarantee the promotion, protection, and recovery of health, in a universal, integral, and egalitarian manner¹. However, there is still difficulty on the part of this system to meet all of the health needs of the Brazilian population. Special emphasis can be given to medication, whose free supply is important to fulfill the principle of comprehensive pharmaceutical services².

Brazilian pharmaceutical services consist of three components related to the financing and procurement of medicines: basic component (aimed at addressing the prevalent and priority health problems of primary health care (APS); strategic component (medicines used to treat endemic diseases); and specialized component (medicines delivery through clinical protocols and therapeutic guidelines)³⁻⁵.

In this sense, the judicialization of health is a strategy used for the application of health products and services, based on the right to health, established by the Federal Constitution of 1988, which advocates that "health is a right of all"⁶. Based on this premise, the Brazilian judicial system often accepts individual demands for claims of medication, provisions, and other health supplies, which are not regularly offered by the SUS. This requirement is because health is considered "a right of all and a duty of the state", which allows both SUS patients and the private system to use lawsuits to obtain medication^{1,7}.

Against this background, medications have been the target of many judicial demands, which compromise the resources destined for the acquisition of medication already made available by the SUS. Studies have shown that among the medication most used in judicial litigation in Brazil, there are those used to treat diabetes mellitus (DM), especially insulin and its analogues⁸⁻¹¹.

DM is a heterogeneous group of metabolic disorders requiring continuous care, with multifactorial strategies for glycemic control and risk reduction, since it can generate micro-vascular and macro-vascular complications¹². In addition to access to medication, a multi-professional team must follow up patients with DM, so that complications and costs are minimized. It has been demonstrated that the costs related to annual pharmacotherapy of patients with uncontrolled DM are superior when compared to those who have control of the disease¹³.

Given the high number of judicial litigations for the application of medication used in the treatment of type 1 diabetes mellitus (T1DM), and the absence of studies evaluating the health services attending these patients, the present study aimed to evaluate the use of public health services by patients with T1DM who receive insulin analogues through lawsuits, before and after this process.

METHOD

A retrospective longitudinal observational study was performed using secondary data obtained from patients with T1DM who acquired at least one of their medications (insulin analogues) through lawsuits, in the municipality of Divinópolis, Minas Gerais state (MG), Brazil. The municipality has an estimated population of 235,977 inhabitants¹⁴. The checklist of Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) was used.

In the judiciary pharmacy of the municipality where medication through the courts is dispensed, there were 89 patients with T1DM who acquired insulin analogues for their treatment through judicial action in the year 2018. All were included in the study. To analyze socio-demographic data and refer to the follow-up of these individuals, information was initially collected from the registers of the judiciary pharmacy and in the Integrated Health System (SIS) of the municipality. This system consists of a secondary database, which provides socio-demographic information about individuals and information on the follow-up of patients in the SUS (consultations, hospitalizations, and examinations). In addition, in order to avoid bias due to a possible lack of information in the database, the records of APS units of SUS patients who did not present information in the registries surveyed (SIS and judiciary pharmacy) were analyzed to evaluate their follow-up.

Participants were classified into two distinct groups referring to the health sector that they use: SUS patients, and patients of a private health system. The SUS patients were considered those who fit into at least one of the following three specifications: 1) attendance in consultations in APS or specialized SUS; 2) laboratory exams performed in the clinical analysis laboratory of SUS; and/or, 3) receipt of medication from the SUS pharmacy. The patients were considered SUS patients if they met some of these specifications in the period before or after the judicialization. If the patient did not meet any of these specifications, they were considered a patient of a private health system.

The information was collected by two researchers; an instrument was developed to facilitate collection. The data collection instrument was composed of two blocks: In Block A, the information referring to the 12 months before the judicial litigation was taken into account, and in Block B, the information referring to the 12 months before the data collection date (October 2018). Since the clinical and laboratory parameters should be performed more frequently, for the laboratory exams and clinical evaluations (blood pressure and capillary glycemia), a period of six months before the judicial litigation was considered in block A and six months before the date of data collection was considered in block B.

The socio-demographic variables (gender, age, and health sector) were collected and the following variables were used to analyze the follow-up of these patients by the SUS: consultations performed in primary and specialized health care, emergency medical consultations, hospitalizations, laboratory exams, and blood pressure and blood glucose measurements before and after judicial litigation. The judicialization time was used to exclude the time interference in the analyses performed and referred to the last instance of the judicial litigation.

Descriptive statistics were performed with categorical variables reported in absolute and relative frequencies. The McNemar χ^2 test with 5% significance was performed to compare the proportions of the variables used for evaluation of the follow-up before and after the trial. In this step, the R program, version 4.4.2 was used.

The present study was approved by the Committee of Ethics in Research Involving Human Subjects (CEPES). CAAE: 87590518.9.0000.5545. Opinion: 2,760,677. July, 8th, 2018.

RESULTS

Among the 89 patients with T1DM who acquired insulin analogues for their treatment through lawsuits, women predominated. Most of the patients presented age between 20 and 39 years and more than half of the patients used only a private health system (55.1%) (Table 1).

Regarding the follow-up of the SUS patients, it was observed that most were not followed up by the system. Before the lawsuit, only 17 (19.1%) patients had consulted in primary care, and 8 (9.0%) patients consulted in specialized care. This number was higher after the lawsuit, in which a total of 27 (30.3%) consulted primary care and 16 (18.0%) in specialized care. The majority of patients also didn't have records of blood pressure, capillary glycemia, and laboratory exams. However, after the lawsuit, there was an increase in the number of these records. The numbers increased from 8 (9.0%) to 12 (13.5%) records of blood pressure; from 3 (3.4%) to 4 (4.5%) records of capillary glycemia, and from 5 (5.6%) to 12 (13.5%) records of laboratory exams. After litigation, there was a decrease in the number of hospitalizations recorded by the SUS: from 5 (5.6%) to one patient (1.1%) and an increase in the number of patients who performed emergency consultations: from 1 (1.1%) to 8 (9.0%).

Regarding the comparison of the analyzed variables before and after the judicial action, it was observed that after the litigation there was a significant increase ($p < 0.05$) in the number of patients who had consultations in APS and emergency medical consultations (Table 2). Judicialization times (when patients received the medicines) were similar for patients who attended (125 months) or not (118 months) primary care consultations after judicialization. This pattern was also observed for emergency consultation (110.5 months) and non-consultation patients (121 months).

Table 1. Distribution of the frequency of patients with type 1 diabetes mellitus (T1DM), who acquired insulin analogues through judicial action in Divinópolis - Minas Gerais, Brazil (n = 89), 2018

Variable	N (%)	
Gender	Female	48 (53.9%)
	Male	41 (46.1%)
Age	0-19 years	19 (21.3%)
	20-39 years	47 (52.8%)
	40-59 years	21 (23.6%)
	≥ 60 years	2 (2.3%)
Sector	Private	49 (55.1%)
	Public	40 (44.9%)

Table 2. Follow up performed by the Unified Health System (SUS), before and after the judicial action, of patients with type 1 diabetes mellitus (T1DM), who acquired insulin analogues through judicial processes in Divinópolis-MG, Brazil (n = 89), 2018

Variable	Before N (%)	After N (%)	p-value
Consultations in primary health care (APS)	At least one	17 (19.1%)	0.043*
	None	71 (80.9%)	
Consultations in specialized public healthcare	At least one	8 (9.0%)	0.065
	None	81 (91.0%)	
Blood pressure measurements	At least one	8 (9.0%)	0.454
	None	81 (91.0%)	
Capillary glycemia measurements	At least one	3 (3.4%)	1.000
	None	86 (96.6%)	
Emergency Medical Consultations	At least one	1 (1.1%)	0.016*
	None	88 (98.9%)	
Hospitalizations	At least one	5 (5.6%)	0.125
	None	84 (94.4%)	
Laboratory exams performed	At least one	5 (5.6%)	0.065
	None	84 (94.4%)	

*McNemar's χ^2 $p < 0.05$

Laboratory exams considered: fasting glycemia, glycosylated hemoglobin, triglycerides, total cholesterol, and fractions
For the variables "consultations in primary health care (APS), consultations in specialized care, emergency medical consultations and hospitalizations", the period used was 12 months before the judicialization and 12 months before the date of data collection
For the variables "blood pressure measurements, capillary glycemia measurements, and performing laboratory exams" the period used was 6 months before the judicialization and 6 months before the date of data collection

DISCUSSION

The present study shows that most of the patients analyzed did not have their T1DM and its complications followed up by the SUS. Because of this, it is noticed that most of the study participants are not SUS patients, but patients of private health services. This finding represents a problem for the management of judicialization of health in the SUS, since some of the objectives of SUS implementation are the promotion of universal access to health services, integrated care, and ensuring equity in the distribution of resources¹². In this sense, universal access to medication without the follow-up of the clinical condition can compromise equity to health, as recommended in the constitution (the same legal precept that guarantees universality), because to provide the medicines via judicial litigation, frequently it is necessary to decrease the resources to the pharmaceutical services components, which can harm other SUS patients. Since the patients with judicial litigation are not followed, the judicial system doesn't know if the treatment is effective or not, that is, if the treatment is necessary¹⁵.

Faced with this gap, Law 12,401/11 was promulgated to recommend that **the dispensation of medication must take place following the protocols and therapeutic guidelines**¹⁶. However, even after seven years of validity of this legislation, its implementation has not been observed, since all guidelines and clinical protocols recommend the follow-up of patients through multi-professional consultations and monitoring of laboratory exams¹². According to the American Diabetes Association¹² and the Canadian Diabetes Association¹⁷, patients with T1DM should be monitored for glycosylated hemoglobin at least twice a year, within a range of three to six months (for adults) and three to four times a year (for children and adolescents)¹²⁻¹⁷. In the present study only 6.5% of patients had glycosylated hemoglobin exams in the pre-judicial period and 13.5% in the post-judicial period performed by the SUS. We do not know the frequency of laboratory tests in private health.

Other studies have also shown that patients of private health systems are the main public of judicial lawsuits in Brazil. They maybe have greater purchasing power and access to private lawyers^{1,6,9,12}.

It is observed that many patients have used lawsuits as a way of transposing the steps, using the SUS only for the acquisition of free or less costly medication, most often prescribed by professionals of the private health system who are responsible for the follow-up of these patients, contrary to the principle of longitudinality proposed by the APS in the SUS¹⁸.

When comparing the variables of care management before and after judicial action, it is noticed that there was an increase in the number of patients who had consultations in APS and emergency medical consultations after the execution of the judicial action. The increase in patients' consultations in the APS would represent a positive point since it could be an indication of greater patient follow-up by the public system. However, even with the increase in consultations, we did not observe any increase in the number of blood pressure and capillary glycemia measures. Furthermore, there was an increase in emergency medical appointments. Given this, it can be seen that access to medication is often not enough if follow-up is not performed, since after the availability of the requested medication, a greater number of patients required emergency care. These situations could be avoided through follow-up by health professionals, as evidenced by Aquino et al.¹⁹, where the empowerment of patients with DM by a clinical pharmacist brought improvements in health and reduced levels of glycosylated hemoglobin and fasting glycemia¹⁹. This can demonstrate the importance of the clinical pharmacist and pharmaceutical care on a patient's quality of life. Furthermore, the clinical pharmacist can also assist in reducing the number of legal proceedings for the access of unnecessary drugs when carrying out pharmacotherapeutic follow-up and instructing patients on the correct way to use the drugs. This can increase their effectiveness, such as human insulins, for example. The length of judicialization does not explain the differences identified, since it was similar in the compared groups.

With an epidemiological transition, there is an increase in non-communicable chronic diseases, which are already considered the main sources of the disease burden in Brazil. Although they are among the most widespread issues in the health area, there is a need for additional actions to manage these diseases, as can be evidenced in the present study among patients with T1DM, since they have access to medication, but their clinical management is not being considered^{20,21}.

According to Mendes²², current health systems are fragmented health care systems, which are incapable of providing continuous attention to the population. Since the judicialization of health ensures access to medicines without follow-up and monitoring reports, there is no guarantee of health to the patients, which can result in a lack of control of chronic diseases, such as DM²².

It is important to emphasize that insulin (neutral protamine hagedorn insulin and regular) is available in the basic component of pharmaceutical services in the SUS. This is why they are not judicialized. However, even with the incorporation of the insulin analogues “asparte” and “glargina” in the specialized component of the state of Minas Gerais²³, the patients analyzed (who judicialized the insulin analogues before the incorporation) continue to receive their insulin analogues via judicial action. This represents a problem in the municipality of study since it harms other patients who depend exclusively on the SUS to carry out their health treatments. Thus, it is necessary to be more careful, not only in the city mentioned but also in the country when analyzing judicial demands to rationalize its process.

The present study shows a higher prevalence of female patients acquiring medication for T1DM by judicial action. This is consistent with findings from other studies concerning the profile of individuals using the judicial service⁸⁻¹¹. These data probably reflect the increased awareness of women seeking health services to guarantee an improvement in quality of life, and therefore, is not a typical characteristic of judicial action⁸. T1DM mainly affects young patients and diagnosis is usually made before 40 years of age¹². This explains the large number of patients aged 20 to 39 years in our study.

To our knowledge, this is the first Brazilian study to take a longitudinal approach before and after the judicialization of medication for T1DM treatment. As a limitation, this study used secondary data and it was not possible to obtain information about patients using private health systems to verify the follow-up of these patients. Moreover, it represents a study conducted in a municipality, which makes it difficult to generalize the results. However, it allowed us to verify the absence of SUS monitoring.

CONCLUSIONS

The majority of patients with T1DM who acquire insulin analogues through judicial action do not use public health to monitor their health problems, and in general, do not present relevant improvement when compared to before and after judicial action. Thus, it can be observed that these individuals most often use the SUS only as a gateway for the acquisition of medications that are needed, without the monitoring of their health problems by the system and contrary to the principle of longitudinality proposed by the APS in the SUS.

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