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ORIGINAL ARTICLE

Management of insulin available by sus: support to control *diabetes mellitus*

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ABSTRACT

Objective: To describe management practices of insulin provided by the SUS and analyze the factors associated with insulin management mistakes. **Method:** Cross-sectional study addressing 113 individuals with *Diabetes Mellitus* from an outpatient clinic in Goiânia, GO, Brazil. Data concerning insulin storage, preparation, and administration were collected from the patients' medical records and classified as appropriate or inappropriate. **Results:** 58.4% of participants were women aged 48 years old on average. Hypertension was reported by 70.8%, and glycated hemoglobin was ≥7% in 89.0%. All the patients made at least one insulin management mistake, and 62.8% made four or more mistakes. The most frequent mistakes were: storing insulin in non-recommended places (46.7%), not injecting insulin 30 minutes before meals (87.5%), not checking for the presence of lumps in the NPH insulin vial (71.9%), and not removing the insulin from the refrigerator between 15 and 30 minutes before injection (88.7%). No significant statistical differences were found among the exposure variables, though women, young individuals, those with 11 or more years of schooling, having the disease for more than ten years, and injecting insulin once or twice a day, more frequently made four or more management mistakes. **Conclusion:** A high prevalence of insulin management mistakes and considerable variability of practices were identified, reinforcing the importance of implementing a DM line of care at all healthcare system levels.

Keywords: *Diabetes Mellitus*. Insulin. Health Care.

INTRODUCTION

Non-communicable diseases (NCDs) are the primary cause of morbidity and mortality worldwide, considerably impacting Health Care Networks[1]. Diabetes Mellitus (DM) is among the four NCDs prioritized by the 2011-2022 Strategic Action Plan for dealing with NCDs proposed by the Brazilian Ministry of Health[2]. DM is considered an epidemic disease worldwide, with a contingent of 628.6 million people up to 2045[3].

The management of DM is complex and demands lifestyle changes (e.g., healthy diet, regular exercises, keeping smoking and alcohol consumption under control) allied with oral medication and/or insulin[3].

Even though the Brazilian Diabetes Society (BDS) and other scientific agencies consider insulin to be the most effective antidiabetic drug[3], the difficulties faced by patients to administer it may result in poor glycemic control[4]. A recent study conducted in the south of Brazil reports that glycated hemoglobin levels were (HbA1c) ≥7% in 69.8% of the patients with DM and the use of insulin was one of the factors associated with this glycemic change[5].

Some studies list difficulties, mistakes, and

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successes in insulin preparation and administration, such as aspiring doses different from the prescribed and not rotating the injection sites, among others[6-9]. Additionally, using a lifted skin fold when administering insulin, which varies according to the individuals' body mass index (BMI), positively influences insulin users' self-care competence[7]. However, there is no evidence of the factors leading to inappropriate handling of insulin in the various stages of its management, which covers from its transportation to administration.

One of the components of the line of care of NCDs, including DM, is providing support to self-care; that is, control strongly depends on the patients' active participation and involvement in the treatment[10,11]. Identifying difficulties to properly using insulin and the factors leading to inappropriate practices can support the DM line of care proposed by the Brazilian plan for coping with chronic diseases, 2011-2022[2] and contribute to the development of specific protocols to manage the insulin provided by SUS, enabling health workers to provide assertive guidance and promote the appropriate and safe use of insulin by patients.

Therefore, the following question guided this study: "What are the precautious users take with the insulin provided by SUS and which are the factors associated with inappropriate practices?" Hence, this study's general objective was to describe how patients manage the insulin provided by the Brazilian Unified Health System (SUS) and analyze factors associated with inappropriate practices.

METHOD

This cross-sectional study addressed individuals with type 2 Diabetes Mellitus (DM2) taking insulin who had a nursing consultation in an endocrinologist outpatient clinic in a public secondary healthcare service located in Goiânia, GO, Brazil. This service provides care to people with metabolic disorders, such as type 1 and type 2 DM, obesity, and thyroid diseases. Patients using primary healthcare services but not able to manage these conditions are referred to this service via the regulation system. Once they access the outpatient clinic, they are scheduled for medical consultation and later for nursing and nutritionist consultations. Approximately 90 slots/month were offered during the study period for people with any endocrinology-related health problem to have their first consultation.

Individuals with DM2 taking Neutral Protamine Hagedorn (NPH) or Regular insulin, aged ≥35 years old, both sexes, having their first nursing consultation during the study period were eligible. Exclusion criteria were individuals with a DM1 diagnosis; a DM2 diagnosis but exclusively taking oral antidiabetic medication; with DM2 but using a pen for insulin application (a device not provided by the public health service); and/or using analogue insulin; or attending a return visit.

Data were collected from the patients' (physical and digital) nursing consultation records from August 2015 and July 2016. The variables in the physical files were standardized according to the recommendations provided by the Ministry of Health and BDS regarding the assessment of people with DM, including personal history, lifestyle, medications, anthropometric measures, and precautions required for the use of insulin. Data of patients were recorded during the nursing consultation, both in the physical and digital records. Additional information was collected from the digital file, where the physicians and nutritionists also record information. In general, the patients presented exams in a period not longer than three months, and the results were recorded on the file at the time of the consultation.

The variables related to insulin management were: 1. Storage (at home, insulin is stored either at room temperature, in the freezer, or refrigerator on the first, second, third shelf or door); 2. Preparation (whether the patient checks for the presence of lumps and homogenizes insulin); and 3. Administration (whether the patient removes insulin from the refrigerator between 15 and 30 minutes before injection, lifts skin fold, applies thermal bag and massage, uses a needle <or> 13 mm, and rotates the sites where insulin is applied.

These practices were classified as appropriate or inappropriate, according to the BDS[1,3] guidelines. In order to establish this study's outcome, the following were considered inappropriate practices:

1. **Storage:** storing insulin on the refrigerator's door or the first or second shelf, in the freezer, or at room temperature;
2. **Preparation:** not homogenizing the insulin in the vial and not checking for the presence of lumps;
3. **Administration:** not removing from the refrigerator 15 to 30 minutes before injection, not lifting a skin fold, not rotating the injection sites, using a needle >13 mm, or massaging and/or applying a thermal bag on the injection site.

The exposure variables analyzed in this study were: demographic (sex, age, and years of schooling)and health condition (duration ofDM2). The following variables were descriptively analyzed: marital status, comorbidities, exercises, smoking, glycated hemoglobin and fasting blood glucose levels, and the use of NPH or Regular insulin.

Exercise, smoking, glycated hemoglobin and fasting blood glucose levels were coded as dichotomous variables. The following question was asked to verify the practice of exercises: "Do you exercise?" and the question concerning smoking was: "Do you smoke?" in which the answers "no" and "former smoker" were classified as "does not smoke". The HbA1c and fasting blood glucose levels were coded according to the BDS's guidelines, that is, HbA1c<7% (under control) and ≥7% (altered); fasting blood glucose<100 (under control) and ≥100 (altered).

Analyzes were performed using Stata 12.0. A descriptive analysis was performed (absolute and relative frequency, mean, standard deviation) along with comparisons using Chi-square or Fisher's Exact test, with the level of significance established at 5%. This study was approved by the Institutional Review Board at the *Hospital das Clínicas* at the Federal University of Goiás (Opinion report No. 1.502.305/2016) and complied with the ethical principles of Resolution 466/2012, National Council of Health (CNS). Data collected from the medical records are confidential, and only the researchers accessed them. Because it is a study using secondary data, the Institutional Review Board waived free and informedconsent forms; a term of commitment to using the data collected from the medical records was asked instead.

RESULTS

Data from 113 people with DM were analyzed considering inclusion criteria and how complete the medical files were. Of these, 58.4% were women, 77% were aged 50+ years old, 56.7% were single/divorced, and 52.7% had six to ten years of schooling. Regarding general health conditions, 70.8% of the participants had systemic arterial hypertension, and more than half had the disease longer than ten years, 77.3% were sedentary, 12.1% were smokers, and the level of glycated hemoglobin of 89.0% was above 7% (Table 1).

Table 1. Description of the sociodemographic data and health conditions of people with DM2 taking insulin, Goiânia, GO, Brazil 2016 (n=113).

Variables	n (%)
Sex	
Women	66 (58.4)
Men	47 (41.6)
Age	
35-49 years old	26 (23.0)
50-59 years old	40 (35.4)
≥ 60 years old	47 (41.6)
Marital status	
Married/Stable union	30 (26.5)
Single/Divorced	64 (56.7)
Widowed	19 (16.8)
Years of education**	
0-5	26 (28.0)
6-10	49 (52.7)
≥11	18 (19.3)
Number of diseases besides DM2	
1-2	21 (18.6)
3 or more	92 (81.4)

To be continued...

Variables	n (%)
Arterial Hypertension	80 (70.8)
Dyslipidemia	72 (63.7)
Thyroid disease	20 (17.7)
Time since DM 2 diagnosis	
< 10 years	42 (42.4)
≥10 years	57 (57.6)
Physical exercise	
Yes	22 (22.7)
No	75 (77.3)
Smoker**	
Yes	12 (12.1)
No	87 (87.9)
HbA1C levels	
Up to 7%	8 (11.0)
≥ 7%	65 (89.0)
Fasting blood glucose levels	
Up to99mg/dl	8 (10.4)
≥ 100mg/dl	69 (89.6)
Taking NPH + Regular insulin	78 (69.7)
Number of daily insulin shots	
1 - 2	34 (31.2)
3 or more	75 (68.9)

Source: Study's data.

Table 2 presents inappropriate practices concerning insulin management as recorded by nurses. The most frequentin appropriate practices include: not applying insulin 30 minutes before meals (87.5%), not checking for the presence of lumps in the NPH vial (71.9%), and not removing the insulin from the refrigerator between 15 and 30 minutes before its application (88.7%). The most frequent appropriate practices included: homogenizing insulin before injection (76.8%) and not massaging and/or applying a thermal bag on the injection site (80.4%). Additionally, 46.7% of the individuals stored the insulin in non-recommended places (on the refrigerator's first or second shelf, refrigerator's door, or freezer), 57.5% used needle>13mm, and 49.4% did not rotate the injection sites.

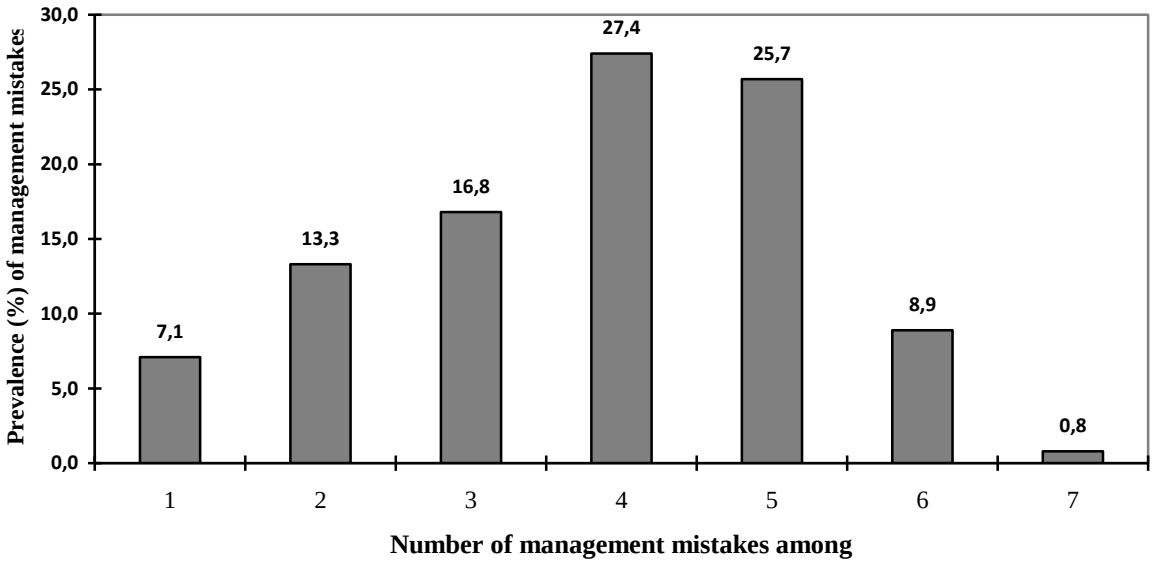
Table 2. Description of inappropriate practices concerning insulin management among people with DM2, Goiânia, GO, Brazil 2016, (n=113).

N	Insulin management	Total (n)	Correct	Incorrect
1	Storing insulin in non-recommended places (refrigerator's first, second shelf, door or in the freezer	105	56 (53.3)	49 (46.7)
2	Not checking for the presence of lumps in the NPH vial	82	23 (28.0)	59 (71.9)
3	Not homogenizing the NPH vial	99	76 (76.8)	23 (23.2)
4	Not removing insulin from the refrigerator between 15 and 30 minutes before injection.	106	12 (11.3)	94 (88.7)
5	Massaging and/or applying a thermal bag on the injection site	92	74 (80.4)	18 (19.6)
6	Using 13mm needles	106	45 (42.4)	61 (57.5)
7	Not rotating injection sites	89	45 (50.6)	44 (49.4)
8	Not applying insulin 30 minutes before meals	96	12 (12.5)	84 (87.5)

Source: Study's data.

Regarding the number of management mistakes, all the patients made at least one mistake, while 62.8% made four or more mistakes (Figure 1).

Figure 1. Number of management mistakes among people with DM2 taking insulin. Goiânia-GO, Brazil 2016, (n=113).



Source: Study's data.

Table 3 presents a bivariate analysis between demographic variables and some health conditions. All the groups present a high percentage of management mistakes. A higher percentage of four or more management mistakes occurred among women, young individuals (35-59 years old), individuals with 11 or more years of schooling, who had the disease for less than ten years, and among those taking insulin once or twice a day. However, no statistical significance was found between these variable.

Table 3. Factors associated with the incorrect use of insulin among people withDM2, Goiânia, GO, Brazil 2016, (n=113).

Variables	Management mistakes		PR (IC95%)	*p*
	1-3	≥4		
Sex				0,835
Women	24 (36.4)	42 (63.6)	0.96 (0.72 – 1.29)	
Men	18 (38.3)	29 (61.7)	1.00	
Age group				0.590
35-59 years old	23 (34.8)	43 (65.1)	1.09 (0.81 – 1.46)	
≥60 years old	19 (40.4)	28 (59.6)	1.00	
Schooling				0.453
0-5 years	12 (46.2)	14 (53.8)	1.00	
6-10 years	18 (36.7)	31 (63.3)	1.17 (0.77-1.78)	
≥11 years	5 (27.8)	13 (72.2)	1.34 (0.84-2.12)	
Duration of DM2				0.517
0-10 years	15 (40.5)	22 (59.4)	1.00	
≥11 years	21 (33.9)	41 (66.1)	1.11 (0.80-1.53)	
Number of insulin injections/day				0.404
1 – 2	10 (29.4)	24 (70.6)	1.00	
3 or more	28 (37.3)	47 (62.6)	1.12 (0.85-1.49)	

Source: Study's data.

DISCUSSION

Individuals taking insulin have many management tasks and this study shows a high prevalence of mistakes. Factors such as sex, age, schooling, and duration of the disease did not appear associated with management mistakes. However, this study's findings reinforce the need to support self-care, provide continuing education to health workers, and monitor the organization of the line of care provided to people with DM in the Health Care Networks.

There is considerable variability in insulin management practices, both in terms of officially recommended practices and management mistakes. However, no studies were found listing the number of mistakes individuals taking insulin usually make. Some studies focus on the specific aspects of insulin management, such as the patients' lack of knowledge regarding injection sites where to inject insulin[12]; improper insulin storage[6,13]; and not rotating insulin injection sites[6]. One hypothesis explaining the many mistakes found refers to the complexity of administering insulin, which demands that precautions are taken from its transportation to administration.

Regarding insulin storage, the BDS recommends it be stored on the refrigerator's middle or bottom shelf or in the vegetable drawer, away from the walls[3]. The habit of storing insulin in the refrigerator's door predominated in this study, followed by storing it at room temperature, in the freezer, and on the first or second shelf. These results are in line with previous studies reporting a predominance of improper storage conditions[14-17]. Insulin appropriate conservation conditions are stressed because otherwise, it will not keep its therapeutic properties and expected effectiveness, compromising patient safety[3]. Additionally, 5% of the participants reported they had stored insulin in the freezer at some point in time, a practice that is highly unsuitable for insulin effectiveness.

Regarding insulin preparation, different procedures were found. Previous studies show that 40.0% of the participants homogenized it by rolling or shaking the bottle intensively[18]. Official guidelines provided by BDSstate that NPH insulin must be carefully homogenized between hands to break up lumps at the bottom of the vial and for the protamine crystals to enter suspension[3].

Concerning insulin administration, 88.7% of the participants injected the insulin while still cold, and 49.4% did not rotate the injection sites. A study conducted in a diabetes center in Italy addressing 352 patients, reports that 46.3% of the participants did not rotate the injection sites, and 34.1% always injected it on the same site of the same quadrant[19].However, studies addressing other health centers report that 75.9%, 82.6%, and 70.6% of the participants, respectively, correctly rotated the insulin injection sites[7,14,20].The BDS recommends that insulin be removed from the refrigerator between 15 and 30 minutes before its application and rotate the injection sites to prevent lipohypertrophy and uncontrolled blood sugar[3].

In this study, the variables sex, age, schooling, duration of the disease, and the number of insulin injections, were tested in bivariate analysis. Some authors suggest that management mistakes may be associated with socioeconomic factors, such as education level[14-16] and the fact that orientation regarding how to manage insulin therapy is not standardized[18], though, no association was foundin this study between education (years of schooling) and management mistakes.

Likewise, sex, age, duration of the disease, or the number of insulin injections were not statistically associated with insulin management mistakes, and no studies were found analyzing these associations. Nonetheless, these results are relevant to implement a DM care plan, including continuing education so that guidelines are correctly followed to ensure patient safety in the use of insulin and its correct administration.

This study presents some limitations. First, a secondary database was used, and the medical records contained incomplete and limited information, which hindered the investigation of other factors potentially associated with the outcome under study. For example, the records did not report information on whether NPH and regular insulin were mixed; the technique used to inject insulin; or whether patients used alcohol or washed hands before the procedure. Another limitation refers to the study's cross-sectional design. Even though it allows analyzing

associations, we cannot infer causality because a temporal sequence cannot be established between exposure and outcome.

CONCLUSION

This study's findings indicate that self-care practices concerning insulin management vary considerably as all the participants performed at least one management mistake, while 62.8% of the patients made more than four mistakes. No significant statistical associations were found between exposure variables and management mistakes.

These findings reinforce the need for providing continuing health education to patients and health workers, both in referral centers and primary health care services, to promote adherence to appropriate self-care practices and ensure the patients' good metabolic control. Supporting self-care, providing continuing education to workers, and monitoring risk factors and insulin management practices are crucial to implementing an appropriate DM care plan to patients within Health Care Networks.

Finally, further studies are needed to analyze the insulin management practices not addressed in this study, such as the aspiration technique, and to assess the difficulties patients face as well as the competence of health workers to assist patients in this process.

CUIDADOS COM O USO DE INSULINAS DISPONIBILIZADAS PELO SUS: SUBSÍDIOS PARA O CONTROLE EM DIABETES MELLITUS

RESUMO

Objetivo: Descrever os cuidados com o uso de insulinas disponibilizadas pelo SUS e analisar os fatores associados aos cuidados inadequados. **Método:** Estudo transversal com 113 pessoas com *Diabetes Mellitus* de um ambulatório de Goiânia-GO. Foram coletados dados em prontuários sobre conservação, preparo e administração de insulina que foram classificados em adequados e inadequados. **Resultados:** Do total de participantes,58,4% eram mulheres e a média de idade foi 48 anos. Hipertensão arterial foi relatada por 70,8% e 89,0% apresentaram hemoglobina glicada ≥7%. A totalidade dos usuários de insulina realizavam pelo menos um tipo de cuidado inadequado e 62,8% realizavam quatro ou mais. Os mais frequentes foram:conservarem locais não recomendados (46,7%), não aplicar insulina 30 minutos antes da refeição (87,5%), não avaliar presença de grumos no frasco de insulina NPH (71,9%) e não retirar a insulina da geladeira entre 15 e 30 minutos antes da aplicação (88,7%). Não houve diferença estatisticamente significante com as variáveis de exposição analisadas, porém a maior proporção de quatro ou mais cuidados inadequados ocorreu nas mulheres, nos jovens, naqueles com 11 ou mais anos de estudo, tempo de doença superior a 10 anos e, entre os que aplicam insulina uma ou duas vezes ao dia. **Conclusão:** Houve alta prevalência de cuidados inadequados e grande variabilidade de práticas, reforçando a importância da implementação da linha de cuidados em *Diabetes Mellitus* em todos os níveis de atenção à saúde.

Palavras-chave: *Diabetes Mellitus*. Insulina. Atenção à Saúde.

CUIDADO EN EL USO DE INSULINAS PROPORCIONADO PORSUS: SUBVENCIONES PARA EL CUIDADO DE *DIABETES MELLITUS*

RESUMEN

Objetivo: describirlos cuidados con el uso de insulinas proporcionados por el Sistema Único de Salud (SUS) y analizar los factores asociados a los cuidados inadecuados. **Método:** estudio transversal con 113 personas con *Diabetes Mellitus* de un ambulatorio de Goiânia-GO-Brasil. Fueron recolectados datos en registros médicos sobre conservación, preparación y administración de insulina que fueron clasificados en adecuados e inadecuados. **Resultados:** del total de participantes, 58,4% era mujeres y el promedio de edad fue 48 años. La hipertensión arterial fue relatada por 70,8%;y 89,0% presentaron hemoglobina glicada ≥7%. La totalidad de los usuarios de insulina realizaban por lo menos un tipo de cuidado inadecuado y 62,8% realizaban cuatro o más. Los más frecuentes fueron: conservar en locales no recomendables (46,7%), no aplicar insulina 30 minutos antes de la comida (87,5%), no evaluar presencia de grumos en el envase de insulina NPH (71,9%) y no sacar la insulina de la heladera entre 15 y 30 minutos antes de la aplicación (88,7%). No hubo diferencia estadísticamente significante con las variables de exposición analizadas, perola mayor proporción de cuatro o más cuidados inadecuados ocurrió entre las mujeres, en los jóvenes, en aquellos con 11 o más años de estudio, tiempo de enfermedad superior a 10 años y, entre los que aplican insulina una o dos veces al día. **Conclusión:** hubo alta prevalencia de cuidados inadecuados y gran variabilidad de prácticas, reforzando la importancia de la implementación de la línea de cuidados en *Diabetes Mellitus* en todos los niveles de atención a la salud.

Palabras clave: *Diabetes Mellitus*. Insulina. Atención de salud.

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