

Quality and safety in the use of insulin therapy by the aged population

Qualidade e segurança no uso da insulino terapia pela população idosa

Calidad y seguridad en el uso de la insulino terapia por parte de la población de edad avanzada

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Abstract: Objective: to evaluate individual and collective quality and safety in the use of insulin by the aged population in a large city of southern Brazil. **Method:** a cross-sectional population-based study conducted in 2016-2017 with older adults aged 68 and over. The interviews were conducted in the older adults' homes. The outcome was measured by the way in which syringes and needles were used and disposed of. Descriptive analysis was performed by calculating the data proportions and projections for the older adults in the municipality. **Results:** 735 older adults were interviewed. The prevalence of diabetes was 20.0%, and 13.8% made use of injectable insulin. Syringes and needle reuse was reported by 55.0%, and 65.0% mentioned discarding the material directly in regular garbage. **Conclusions:** the quality and safety of the older adults in insulin therapy are compromised, and it is necessary to implement health education strategies aimed at improving knowledge and access to the appropriate guidelines.

Descriptors: Aged; Diabetes Mellitus; Insulin; Disposable Equipment; Patient Safety

Resumo: Objetivo: avaliar a qualidade e segurança individual e coletiva no uso de insulina pela população idosa em um município de grande porte do sul do Brasil. **Método:** estudo transversal de base populacional realizado em 2016-2017 com idosos de 68 anos ou mais. As entrevistas foram realizadas nos domicílios dos idosos. O desfecho foi

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medido pela forma de utilização e descarte das seringas e agulhas. Realizou-se análise descritiva mediante cálculo das proporções e projeções dos dados para os idosos do município. **Resultados:** foram entrevistados 735 idosos. A prevalência de diabetes foi de 20,0%, e 13,8% faziam uso de insulina injetável. A reutilização das seringas e agulhas foi relatada por 55,0% e 65,0% referiram descartar o material direto no lixo comum. **Conclusões:** a qualidade e a segurança dos idosos em insulino terapia estão comprometidas, sendo necessário implementar estratégias de educação em saúde que visem melhorar o conhecimento e acesso as orientações adequadas.

Descritores: Idoso; Diabetes Mellitus; Insulina; Equipamentos Descartáveis; Segurança do Paciente

Resumen: Objetivo: evaluar la calidad y la seguridad individual y colectiva en el uso de insulina por parte de la población de edad avanzada en un importante municipio del sur de Brasil. **Método:** estudio transversal de base poblacional realizado en 2016-2017 con ancianos de al menos 68 años de edad. Las entrevistas se realizaron en los domicilios de las personas de edad avanzada. El resultado se midió considerando la forma de utilización y descarte de las jeringas y agujas. Se realizó un análisis descriptivo mediante el cálculo de las proporciones y proyecciones de los datos para los ancianos del municipio. **Resultados:** se entrevistó a un total de 735 personas de edad avanzada. La prevalencia de diabetes fue del 20,0%, y el 13,8% utilizaba insulina inyectable. El 55,0% indicó que reutilizaba las jeringas y agujas y el 65,0% mencionó que desechaba el material directamente en la basura común. **Conclusiones:** la calidad y la seguridad de las personas de edad avanzada sometidas a insulino terapia están en riesgo, por lo que resulta necesario implementar estrategias de educación en salud que tengan por objetivo mejorar el conocimiento y el acceso a las pautas adecuadas.

Descriptor: Anciano; Diabetes Mellitus; Insulina; Equipos Desechables; Seguridad del Paciente

Introduction

Worldwide, it is estimated that 415 million people have a medical diagnosis of Diabetes Mellitus (DM).¹ Data from the International Diabetes Federation in 220 countries verified that the prevalence of Type 2 DM in 2015 varied from 4.3% in Africa, 7.0% in Europe, and 9.1% in Central and South America, to 12.7% in the Middle East and, worldwide, the prevalence was 8.2%.² In Brazil, currently 6.9% of the population suffers the disease, which represents more than 13 million people.¹

Genetic and behavioral conditions are the most common risk factors for the occurrence of diabetes, and the disease is characterized by an increase in the glycemic levels that occurs due to deficiency in the production of insulin or in its action in the body.³⁻⁴ In the control of the levels of glucose, hyperglycemia or hypoglycemia can occur, and many individuals with DM use oral or injectable drugs to regulate blood glucose levels in the body, such as insulin.^{1,4}

Needle reuse in insulin application is a concern due to the possibility of causing pain, bleeding and increased risk of contamination.¹⁻² When used daily, it requires some basic care

measures to ensure safety and quality in the application. The recommendations are still divergent and there is no consensus between the Ministry of Health (*Ministério da Saúde*, MS) and the Brazilian Diabetes Society (*Sociedade Brasileira de Diabetes*, BDS). The first guides the use of disposable syringes and needles up to eight times by the same person; however, the SBD recommends that the latter be for single use and discarded immediately after use.^{1,4}

Disposal of needles and syringes must be carried out in specific containers for sharps or rigid wide-mouth plastic vials, and discarded as contaminating material by the health services.⁵ Most of the times, home disposal is carried out in household garbage and in unsuitable containers causing biological, household and environmental risks, in addition to the possibility of causing accidents in their handling by waste pickers or urban collection workers.⁶

In East Africa, a study using information from the EADSG (East African Diabetes Study Group) advises that syringes and needles must be used only once but, if reused, they should not be used more than five times. Safe disposal must be guided by the health professionals and it is the patient's responsibility to separate into puncture-proof collection boxes. Subsequently, the material must be disposed of by the manufacturers themselves for their proper purposes.⁷

Patient safety regarding insulin use is characterized by a set of actions to avoid, prevent and minimize problems arising from care and interventions.⁵ Insulin-dependent users perform daily insulin applications; for this, they need guidelines that include the proper technique of the injectable application and the ways of storing and disposing of the material in order to ensure safe use.

For many years, the theme regarding syringe and needle reuse and the disposal of the material was considered a health problem and remains current and relevant.¹ Therefore, this study answers the following question: “How can quality and safety in insulin use be assessed by the aged population of Bagé?” In this sense, the objective is to assess individual and collective quality and safety in the use of insulin by the aged population in a large city of southern Brazil.

Method

This is a cross-sectional population-based study in an area covered by primary health care services. This article used data collected in the follow-up of the cohort study entitled “Health of the Aged *Gaúcho* from Bagé, RS” (“*Saúde do Idoso Gaúcho de Bagé, SIGa-Bagé*”), which aimed to identify changes in the health situation of the older adults and the contributions of the Family Health Strategy (FHS) in meeting the health needs of the Bagé urban area in the period from 2008 to 2016/2017.

The municipality of Bagé is located in the South of the state of Rio Grande do Sul (RS), 393 km from the state capital, Porto Alegre. The estimated population in the municipality at the time of data collection (2017) was 122,209 inhabitants, the Human Development Index (HDI) was 0.740, and the mean life expectancy at birth was 75.9 years old.⁸ The municipal health system in 2017 was composed of 19 Basic Health Units (BHUs) with FHS units and 3 traditional units located in the urban area of the municipality.⁹

The sample consists of older adults aged 68 or over, interviewed in the baseline study of the cohort constitution in 2008, in which the inclusion criterion was being at least 60 years old. The older adults excluded were those who were institutionalized, had moved to another city or were traveling during data collection.

The sample size in 2008 was calculated considering 10% of losses and refusals, a design effect of 1.3, and 80% power to detect relative risks of 1.5 exposures that affected at least 4% of the population. The sampling process took place in multiple stages. Initially, the sample was located from the coverage area of each BHU and was later divided into micro-areas, with numerical identification of each block, with a random draw of the initial point of data collection. In order to ensure that all the households had the same probability of composing the sample and ensuring dispersion in the territory, a systematic jump of one in five households was used.¹⁰

This study uses the data collection from the follow-up of the cohort that took place from September 2016 to August 2017, in order to contact the older adults interviewed in 2008. Data collection was conducted by interviewers who were previously qualified and trained and was carried out at the older adult's own home. The interviewers had a list with the name, telephone number, address and reference BHU of the older adults, for the purpose of contacting them. A structured electronic questionnaire with pre-coded questions was used, standardized, previously tested, and applied using a Personal Digital Assistant (PDA) digital device. The complete instrument consisted of 757 open and closed questions, in addition to anthropometric measures.

Before data collection in 2016/2017, a pilot study was carried out with older adults from a long-term institution in the municipality of Bagé in order to test the instruments, the instruction manual, the organization of the field work and the performance of the interviewers. The logistics provided for three attempts to locate the older adult and apply the questionnaire; otherwise, it was considered as a loss/refusal, with no substitutions allowed.

To assess the outcome - quality and safety in the insulin use process - the following questions were used: Do you use the syringe again? (no/yes) If yes, how many times?, How do you discard (throw away) the syringe? (directly into regular garbage/put the needle and syringe in a rigid container and put it in regular garbage/put the needle and syringe in a rigid container and take it to the BHU/put the needle and syringe in a rigid container and hand it in to a Community Health Agent (CHA) or another professional who performs the home visit/other, which?

Insulin-dependent older adults were identified through the following questions: At some point in your life, did a doctor say that you have Diabetes, (blood sugar), even if controlled? (no/yes). For the older adults who answered "yes", the following question was asked: Do you use injectable insulin? (no/yes), Who applies the insulin to you? (myself/family member/health professional/other, who?

For analysis purposes, quality in insulin use was considered when the older adults used the syringe and the application needle only once, not reusing the material as instructed by the SBD and by the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA) in Resolution (RE) No. 2,605.29 of August 11th, 2006.^{1,11} Regarding storage and disposal, the process was considered safe when the sharps were stored in rigid material and delivered to the BHU, taken to the service or handed in to some professional on a home visit in accordance with Resolution of the Collegiate Board (*Resolução da Diretoria Colegiada*, RDC) No. 306, of December 7th, 2004.¹²

To compose the descriptive analysis, the following demographic, socioeconomic, morbidity and health status variables were used: gender (male/female), age: (68 - 79 years old/ \geq 80 years old), skin color (white/black, yellow, brown, indigenous), schooling (none/1 to 7 years/ \geq 8 years); socioeconomic classification according to the criteria of the Brazilian Association of Research Companies (*Associação Brasileira de Empresas de Pesquisa*, ABEP) (A and B/C/D and E),¹³ retirement (no/yes), marital status (with a partner or married; without a partner; single/widowed), lives alone (no/yes), self-perceived health (terrible and bad/regular/excellent and good), health plan (no/yes) and type of coverage BHU (Traditional/FHS).

Data analysis was performed using the Stata 12.0 statistical program (StataCorp/College, United States of America). Descriptive statistics were used in the analysis, with calculation of the proportions and their respective confidence intervals (95% CI). Subsequently, the values were calculated through projection using Microsoft Excel®, for the aged population of the municipality of Bagé above 65 years old, using data from the Economics and Statistics Foundation (2017).¹⁴

The research was conducted in accordance with the required ethical standards (MS Resolutions 466/2012 - 510/2016 - 580/2018) and the study was submitted to *Plataforma Brasil*,

evaluated by the Research Ethics Committee of the Medical School at the Federal University of Pelotas, and approved under opinion No. 678,664 on May 29th, 2014.

Results

In 2016-2017, 735 older adults were interviewed. Of the aged individuals who were not interviewed in the second follow-up, 81 (5.1%) were refusals and 220 (13.8%) were losses (including those not located, institutionalized, who moved to another municipality, and losses in data transfer). The sample consisted mainly of women (65.4%; n=481) and white-skinned older adults (82.2%; n=604). The mean age was 77.2 years old (SD±6.2 years old). As for the socioeconomic classification (ABEP), 46.1% (n=332) were in the D/E strata. Self-perception of excellent/good health was reported by 53.7% (n=382) of the sample and 54.4% (n=400) of the older adults were covered by the FHS (data not shown in the table).

Table 1 shows the relative frequencies (%) of the older adults with a medical diagnosis of DM and using insulin. It is observed that half were male (n=10), three quarters (n=15) were aged between 68 and 79 years old, most were white-skinned (n=17) and had between 1 and 7 years of study (n=14). Half of the older adults (n=10) were from socioeconomic class D/E, most were retired (n=18) and did not live alone (n=14) and, in addition, most of them lived in the FHS coverage area (n=14) (Table 1).

Table 1 - Description of the sample according to the demographic and socioeconomic characteristics of the insulin-dependent older adults. Bagé/RS, 2016/17 (n=20).

Variable	N	%
Gender		
Male	10	50.0
Female	10	50.0
Age		
68 - 79 years old	15	75.0
≥80 years old	5	25.0

Skin color		
White	17	85.0
Black, yellow, brown, indigenous	3	15.0
Schooling		
None	2	10.0
1 to 7 years	14	70.0
≥8 years	4	20.0
Socioeconomic classification		
A/B	2	10.0
C	8	40.0
D/E	10	50.0
Retirement		
No	2	10.0
Yes	18	90.0
Marital status		
With a partner/Married	8	40.0
No partner/Single	5	25.0
Widowed	7	35.0
Lives alone		
No	14	70.0
Yes	6	30.0
Self-perceived health		
Terrible/Bad	1	5.2
Regular	15	79.0
Excellent/Good	3	15.8
Health plan		
No	13	65.0
Yes	7	35.0
Type of coverage BHU		
Traditional	6	30.0
FHS	14	70.0

N: Absolute frequency; %: Relative frequency; BHU: Basic Health Unit; FHS: Family Health Strategy.

The prevalence of DM was 20.0% (95% CI: 17.1; 22.9); the use of injectable insulin was reported by 13.8% of the older adults (95% CI: 8.1; 19.5); when asked who applied the insulin, 65.0% (95% CI: 42.1; 87.9) reported that they applied it themselves and 25.0% (95% CI: 4.2; 45.8) some family member (Table 2). Syringe and needle reuse was reported by 55.0% of the older adults who used injectable insulin and reused the equipment twice or more times. Regarding the disposal of sharps, 65.0% discarded them directly in regular garbage, 15.0% burned the

material, and 10.0% put it in a rigid container and discarded it in regular garbage, and put it in a rigid container and took it to the BHU or handed it in to a health professional (Table 2).

Table 2 also shows the projection of the outcomes under study based on the estimated population of 14,586 older adults over 65 years old in Bagé.¹⁴ Using the prevalence of the sample, the estimated total number of aged individuals diagnosed with DM in the city would be 2,917. Extrapolating the percentages of this study, nearly 397 older adults would use insulin to control diabetes and approximately 258 would perform self-application. Projected material reuse would be carried out by 218 older adults, of which 179 would use it twice and 40, three times. As for the disposal of the material, a total of 258 older adults would dispose of syringes and needles directly in regular garbage.

Table 2 - Prevalence of the outcome variables of the 2016/17 SIGa-Bagé study and extrapolation to the aged population living in the urban area of the municipality of Bagé. 2016/17 (n=735).

Variables	SIGa-Bagé 2016/17 data		Projections for older adults > 65 years old in Bagé, RS
	N	%	N
Diabetes (n=734)			
Yes	147	20.0	2,917
No	587	80.0	11,669
Use of insulin (n=147)			
Yes	20	13.6	397
No	127	86.4	2,521
Application (n=20)			
Older adult	13	65.0	258
Family member	5	25.0	99
Others	2	10.0	40
Reuse (n=20)			
Yes	11	55.0	218
No	9	45.0	179
Number of times (n=11)			
2 times	9	81.8	179
3 times	2	18.2	40
Disposal (n=20)			
Directly in regular garbage	13	65.0	258
Burn	3	15.0	60
Rigid regular garbage container	2	10.0	40

Rigid container in the BHU	2	10.0	40
Total	735	100.0	14,586*

N: Absolute frequency; %: Relative frequency; SIGa-Bagé. *Number of older adults in Bagé according to the Economy and Statistics Foundation, 2017.¹²

Discussion

Among the main results, it is noteworthy that needle and syringe reuse and the incorrect disposal of sharps compromise the quality of the process and the safety of the application and disposal related to insulin use.

In this study, it was verified that one fifth of the older adults had a diagnosis of DM, observing that, in the period from 2001 to 2017, prevalence varied between 6.2% and 22.4% in Brazil.¹⁵⁻¹⁸ According to data from the Mortality Information System (*Sistema de Informação sobre Mortalidade*, SIM) in 2016 in the municipality of Bagé, cardiovascular diseases accounted for 34% of the deaths, with DM being responsible for 9%. In addition, 5,092 patients were registered in the Primary Care Information System with a DM diagnosis in the year.⁸

It is verified that, despite the years gone by, the number of patients diagnosed with diabetes continues to increase, in addition to the deaths caused by the disease itself. And even with the guidelines and provision of information on daily practices for sugar control, such as care in food and physical activity, there are individuals who are unable to put them into action, not attaining any change in their lifestyle. In addition to passing on the guidelines, it is necessary that the health professionals are aware of other reasons that lead these people to not making these changes considered simple and effective, such as environmental, economic and social factors.^{4,19}

In São Paulo, in 2001 and 2002, 1,949 older adults were interviewed, 19% of whom were insulin users.¹⁶ In a comparative study with data from the Surveillance of Risk and Protection Factors for Chronic Diseases by Telephone Survey (Vigitel), the prevalence of insulin use in 2012 and 2016 was 17.6% and 19.7%, respectively.²⁰ According to the studies found in the literature,¹⁵⁻

¹⁸ the prevalence of the use of insulin therapy has not changed over the years and has remained stable, as has the prevalence of the disease. In Bagé, approximately one out of seven older adults made use of injectable insulin. The prevalence values reinforce the need for the health professionals and the informal support network to be attentive to the practice of insulin application, to follow the prescription correctly, when applying the daily dose, and paying attention to local asepsis and hand hygiene.

As for the reuse of the needle and syringe for application, it was observed that more than half of the older adults in this study reused the material, which compromises quality of care. In Cajazeiras (Paraíba) in 2015, a study conducted with 15 insulin users aged between 10 and 85 years old verified that 80% reused needles and syringes, ranging from 2 to 15 applications with the same material; 50% of the users justified reuse due to the fact that the Unified Health System (*Sistema Único de Saúde*, SUS) did not provide the material, and the others referred to the financial condition and/or cost of the material.²¹ Another study carried out in Porto Alegre (Rio Grande do Sul) in 2017 with 168 insulin-dependent diabetics and family members responsible for the application of insulin, the reuse of sharps was referred to by 93.4% of the individuals, with some of them mentioning reusing them for up to 30 days.²²

The SBD,¹ the World Health Organization²³ and the manufacturers themselves identify needles and syringes as single-use materials, which differs from the MS recommendation,⁴ which authorizes reuse of these materials provided that it is done with due care.

In the municipality of Bagé, the health professionals from the BHUs follow the MS guidelines to guide users with diabetes on insulin therapy. It is noteworthy that the disposable material is not available in full in the public health network, making it difficult for the population to daily apply the medication.

Some patients choose to reuse insulin needles for convenience, economy, lack of supplies and environmental concern. Needle reuse causes changes such as: loss of lubrication and

sharpening, changes in the bevel, risk of breaking the needle during application, and blockage of the flow due to insulin crystallization.¹

The older adults in this study reused needles and syringes for less time in comparison to the other studies with insulin users, although falling short of what is recommended.²¹⁻²² It is observed that the BHUs in the municipality of Bagé are mostly FHS, which ends up benefiting the bond with the users, and can indicate greater provision of guidelines by the health professionals in an accessible way for the understanding of the target population.

In the aforementioned study, bacteriological analysis was performed on 20 reused sharps needles and the authors identified that, after 24 hours of material incubation, 45% of the needles showed bacterial growth confirming contamination, and 46.7% of the studied population reported not performing any hygiene care, including hand washing for the application. And it is noteworthy that 60% of the older adults reported some reaction at the application site, mentioning bleeding, erythema, hematoma, edema and lipodystrophy.²¹

Therefore, contamination of sharp materials compromises quality and safety in the use of insulin and requires guidelines on hygiene care measures and investment in the supply of material in sufficient quantity. The risks of this contamination are great; depending on the colonized bacteria, it can cause abscesses and leakage into the bloodstream, which can cause the death of some cells, local or systemic infection and, consequently, hospitalization.²¹

As for the home disposal of sharps, a safety marker in this study, it was observed that almost the entire population did not discard them properly in an appropriate container or return them to the BHU for proper disposal.

In the study developed at the endocrinology outpatient clinic of a teaching hospital in Campinas (São Paulo) with 70 insulin-dependent individuals, 34.3% reported putting the materials in a container and taking them to the BHU, 51.4% of the individuals reported discarding the material in the household garbage, and 14.3% burned the garbage; questions were

also asked about knowledge on household and biological waste, and only 5.7% of the interviewees knew the difference.²⁴ In Fortaleza (Ceará), a study selected 143 Insulin therapy users between 2014 and 2015 and verified that 57.1% of the interviewees discarded sharps in regular garbage and 48.6% of the users reported receiving guidelines on correct disposal during the consultations where, in 90.0% of the cases, the nurse was the person offering this guidance. In addition, 2.9% of the interviewees reported that accidents had already occurred with the household residents due to improper disposal of the material.²⁵

As a result of the degrading potential, polluting against the environment and infectious against the health of the population that may come into contact with these materials, waste from the health services, such as sharps, requires special care and correct handling and management techniques. Incorrect disposal can also lead to the proliferation of vector insects and to direct contamination of the professionals who handle the garbage, in addition to environmental tragedies, especially during periods of heavy rain.²⁶

Concern for the environment has been observed since 1992 with the launch of Agenda 21, an action plan for building a sustainable society combining methods of environmental protection, social justice and economic efficiency, signed by 179 countries during the United Nations Conference on Environment and Development (ECO-92) and also reinforced by the 2015 “Sustainable Development Goal”, taking into account one of the most important issues for maintaining the quality of the environment: proper waste management.²⁷⁻²⁸

The extrapolation of the prevalence values to the population scope presented in the article reinforces the magnitude of the problem from a population sample. Projecting the results has the potential to assist in the organization of integrated public policies, in order to protect human life and the environment. Through this information, it is possible to think about health education strategies in the care of the older adult with diabetes and to show the serious public

health problem that reflects in the individual care of each patient, leading to complications that generate hospitalizations and avoidable exposures.

As for the extrapolation referring to the disposal of the material, the data show that, if projected for the entire aged population with DM in Bagé, the absolute number of users who can dispose of it inappropriately is high, which, in addition to the environmental consequences, puts workers who handle contaminated waste at risk. Thinking broadly facilitates a critical look at the results and causes greater impact on data dissemination, seeking to develop actions to promote the health of the older adults, caregivers and professionals for comprehensive care and for improving the health of the population and the handling of material, in order to prevent environmental risks and contamination of other individuals.

In this context, the main focus is to work with education in health aimed at greater autonomy of the users, integration with public health services and prevention of harms, in the search for adequate living conditions, as it allows each person to be responsible for reducing the individual and collective risks.

It is necessary to implement educational strategies aimed at people with diabetes and their family members, with the objective of disseminating self-care practices, developing skills, attitudes and behaviors for the management and control of the disease, in addition to improving the quality of life of the patients and to delay complications.²⁸⁻²⁹

As positive points, the percentage found for this representative sample of older adults stands out and projecting it for the total of aged individuals in the municipality, being possible to observe the magnitude of the problem and to obtain an overview of the reuse and disposal situation of these materials, providing indicators for evaluating quality and safety in the use of insulin therapy, in addition to the population-based design and methodological rigor employed in planning and collecting data.

Some limitations in this study must be considered, such as the “n” of the outcome, considered small for the analyses of associations with the independent variables. Another limiting factor was the scarce publication of articles on the themes, compromising the discussion with current articles.

Conclusion

The results of this study show that adequate quality and safety in relation to the use and disposal of sharps by insulin-dependent individuals was compromised in the municipality of Bagé, with more than half of the older adults reusing and discarding the material in the wrong way.

These items are suitable for adaptation through simple interventions such as education in health. It is noteworthy that the data found can assist in making management decisions for the organization of the health network and investments in effective actions, as well as assist the professionals in the formulation of the work process, based on evidence to guide the population on the correct use and disposal of materials for insulin-dependent individuals.

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