

Pilot trial on the detection of patients with undiagnosed diabetes mellitus type 2 performed in community pharmacies in Valladolid. Environmental impact evaluation

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KEYWORDS

Capillary blood sugar, carbon footprint, Findrisc test, screening, type 2 diabetes, Community Pharmacy

ABBREVIATIONS

ADA: American Diabetes Association
BMI: Body mass Index
cm: centimeters.
CO₂: Carbon Dioxide
dL: deciliters
DM2: Diabetes mellitus type 2
kg: kilograms
km: kilometres
mg: milligrams
NICE: National Institute for Health and Care Excellence
SD: Standard Deviation
SED: Sociedad Española de Diabetes

ABSTRACT

Introduction: The complications that DM2 can develop, and the undiagnosed population (6%) highlight the importance of screening at the population level. The aim of this work is to evaluate and verify whether the professional activity performed in pharmacies is a good point to detect patients with undiagnosed type 2 diabetes mellitus and to refer them for a possible diagnosis. Moreover, to evaluate the environmental impact of the actions.

Methodology: Findrisc questionnaire for patients who met the inclusion criteria and agreed to participate in the study. Basal capillary blood glucose measurement if the result was ≥ 15 points and referral to a physician if blood glucose was ≥ 110 mg/dL.

Results: 44 pharmacies participated. The sample included 434 users; those with high or very high risk (Findrisc ≥ 15) underwent capillary basal glycemia, with a mean result of 124.51 mg/dL (SD=33.6). Out of the 89 patients referred to the physician (20.5%), the patients diagnosed with diabetes type 2 accounted for 3% of the analyzed sample.

Conclusions: The number of newly diagnosed patients (3%) reflects that the community pharmacy is a good place for diabetes detection. In addition, the study reveals pharmacists' usefulness in their role as a health educator, since they provide guidance on healthy lifestyle habits to those patients not subject to physician referral. Furthermore, closer collaborations between physicians and pharmacists would be necessary in diabetes screening, since the return of information was low; although we can observe that in rural areas, where the relationship is close, the return rate was 85.2%.

INTRODUCTION

In the Di@betes study performed in Spain to ascertain diabetes prevalence, it was estimated that approximately 30% of the population had some type of abnormality in carbohydrate metabolism. According to data from this study, the global prevalence of diabetes mellitus adjusted for age and sex was 13.8%; approximately half (6%) was undiagnosed diabetes mellitus (1).

The symptoms of this disease, in general, have a low intensity or may even not manifest themselves, whereby high blood glucose levels can lead to various complications (2). Not knowing the diagnosis of this disease often involves a long time during which (3,4) these patients could present a high risk of developing macrovascular and microvascular complications (5,6). For this reason, early detection and commencing treatment as soon as possible to reduce the course and complications of this disease are so important (7,8).

Screening tests to determine diabetes are recommended by institutions such as the NICE (9), Canadian Task Force (10), ADA (6) and SED (11).

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The risk of suffering diabetes can be determined by the Frindisc questionnaire, one of the most commonly used tools because it is a non-invasive technique that enables identifying patients at higher risk of developing diabetes mellitus type 2 (DM2) and if necessary, performing complementary tests to determine the diagnosis of undiagnosed DM2; or, on the other hand, following them up periodically to try and delay disease onset (11–13). In Spain, the capacity of this test was validated by means of the Pizarra study in 2012 (14).

At the moment knowing the environmental impact of the activities performed is very convenient, since the health sector accounts for 4.4% of global CO₂ emissions, putting it in fifth place in terms of contribution of emissions to the atmosphere (15–17). This is especially important in rural areas, where doctors, appointments or medical consultations are not so available, and patients sometimes need to move to other towns to undertake certain medical tests or pick up the results.

The measurement of clinical parameters, as well as disease prevention by performing screening and detection of hidden diseases or disease risk, are some of the services provided by the pharmacist in relation to health (18). Performing this type of test in the community pharmacy helps to rationalize health spending and improve the quality of life of patients (15–17,19), particularly in rural areas, where avoiding travel for a capillary blood glucose determination benefits the patient and the environment; CO₂ emissions are reduced.

The aim of this study is to evaluate the results of a DM2 detection programme from community pharmacy using the Findisc test and in applicable cases determination of capillary blood glucose; and refer them, if applicable to their health centre for a possible diagnosis. As a secondary objective, analyzing the environmental impact of the action performed is proposed.

MATERIAL AND METHODS

Epidemiological, observational, cross-sectional study performed in the pharmacies of Valladolid from 10 to 30 November 2021.

Taking part in the study was offered in general and voluntarily to all pharmacies in Valladolid. Those pharmacies that agreed to participate (15.7%) received specific online training on the procedure to perform. The Findisc test was made available to fill in with each participant and data was subsequently transferred to an online questionnaire created for having all the data collected.

The Findisc test was performed on people who met the inclusion criteria: person who visits the pharmacy, aged over 18, not previously diagnosed with diabetes

and who agreed to voluntarily take part in the study. If the total score obtained was <15 points, pharmaceutical advice was offered on healthy lifestyle, diet and exercises. In cases with results >15 points, the participant was offered the possibility of returning the following day in a fasting state to undertake a basal capillary blood glucose after signing the corresponding informed consent. This test was performed by capillary puncture and measured with validated and self-calibrating glucometer Glucomen® Aereo 2K from A. MENARINI diagnostics. If basal capillary blood glucose was ≥110 mg/dL (20,21) the participant was referred to the physician to confirm the possible diagnosis of DM2 by HbA_{1c} analysis. Those patients who were referred to the physician were given a derivation sheet and asked to return to the pharmacy to be informed about the results obtained.

The result obtained in the Findisc test was considered as the primary endpoint. Subgroups were set out according to result.

- Low risk: <7 points.
- Slightly high risk: 7–11 points.
- Moderate risk: 12–14 points.
- High risk: 15–20 points.
- Very high risk: >20 points.

Finally, it was analyzed whether or not there was confirmation of DM2 diagnosis in patients referred to the physician.

Height and weight were measured with approved scale with built-in height rod and waist circumference using a flexible tape measure. The measurement was taken at navel height.

Figure 1 shows the study's general outline.

Environmental impact measurement

The distance from each pharmacy to its reference health centre where patients would be referred if necessary was determined by Google Maps.

The terra.org calculator was used to determine the carbon footprint saved by pharmacies using this intervention. For city movements, calculations were made by selecting bus as a means of transport (intermediate between the routes travelled on foot or by private car). The calculator used indicated that 1 km covered by a bus generates 0.0620091 kg of CO₂. However, in the rural area the traditional car was selected as means of transport due to less availability of public transport. For these calculations, over a 1 km journey, a consumption of 0.1899847 kg of CO₂ was estimated.

The number of transfers avoided was calculated as follows:

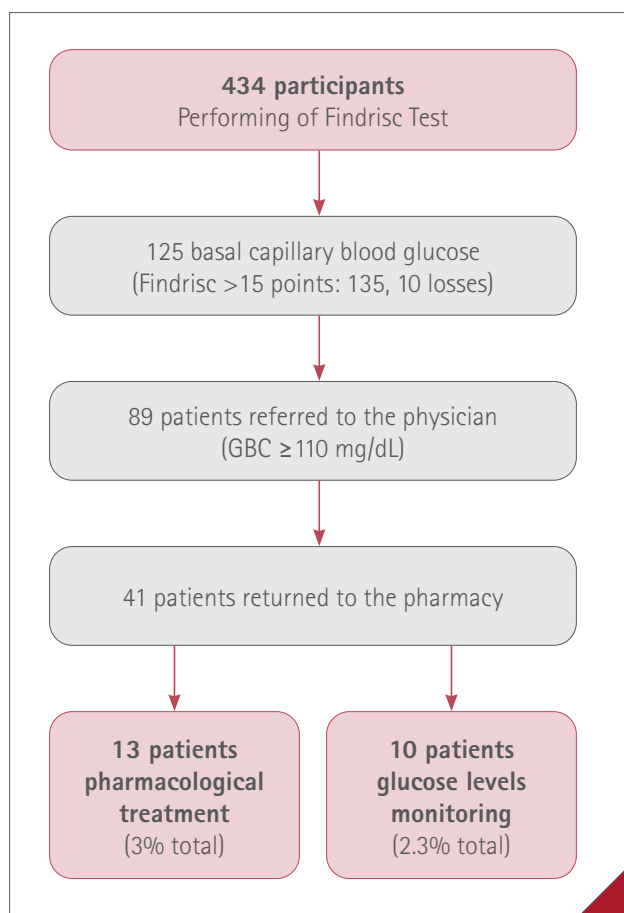


Figure 1 General scheme of the study

- For participants who did not need to be referred to the health centre, two transfers were avoided.
- For participants who were referred to the health centre, twice as many trips were avoided, that is, four transfers.

Once all the km saved with the pharmacy interventions were added, that figure was multiplied by CO₂ consumption over 1km travelled (CO₂ factor) and by two in total cases not referred or by four in those cases referred to the physician. Finally, all the results were added to ascertain the total CO₂ saving and divided between the 20 days the intervention lasted to find out the daily average.

Statistical analysis

The mean and standard deviation of the total score of the Findrisc test and measurements of basal capillary glycemia were calculated.

RESULTS

A total of 44 pharmacies in the province of Valladolid took part in the study, 16 of which were in the rural area and the remaining 28 urban. They represented 15.7% of pharmacies

in the province. The collaborating pharmacists totalled 58, considering that in some pharmacies, more than one pharmacist participated in the study.

A total of 434 cases were collected. The characteristics of the population studied are listed in **Table 1**, which includes the responses after performing the Findrisc test.

Table 1 Characteristics of the population taking part in the study (Results of the answers to the Findrisc questionnaire of the 434 study participants.)

Age	N=434	%
<45	70	16.1
45-54	92	21.2
55-64	125	28.8
>64	147	33.9
BMI		
<25	96	22.1
25-30	194	44.7
>30	144	33.2
Waist circumference (cm)		
F <80 M <94	67	15.4
F 80-88 M 94-102	125	28.8
F >88 M >102	242	55.8
Physical activity		
Yes	272	62.7
No	162	37.3
Fruits		
Yes	326	75.1
No	108	24.9
Hypertension medication		
Yes	159	36.6
No	275	63.4
Previous high blood glucose levels		
Yes	71	16.4
No	363	83.6
Family history of diabetes		
1st degree	165	38.0
2nd degree	82	18.9
No	187	43.1

More than 80% of study participants are older than 45 years old and approximately 60% were women. Regarding the considered risk factors for this disease, more than 75% of participants presented BMI greater than 25, while approximately 85% have waist circumference above normal.

Of the 434 tests performed, with a mean of 12.5 (SD=4.5), in 135 results were obtained with high or very high risk (Table 2). Of the candidate participants for basal

Table 2 Score obtained in the Frindrisc test

Risk level. Frindrisc score	Number of participants	% total
Low (<7)	44	10.1
Slightly high (7-11)	134	30.9
Moderate (12-14)	121	27.9
High (15-20)	124	28.6
Very high (>20)	11	2.5

Table 3 Capillary blood glucose results

(Capillary blood glucose results performed on the study participants who obtained a Frindrisc test score equal or higher than 15 points)

Capillary blood glucose	Number of participants
<110 mg/dL	36
≥110 mg/dL	89

Table 4 Physician referral results

Physician referral results	Participants
Establishment of pharmacological treatment	13
Glucose level monitoring	10
Diet and physical activity advice	18

Table 5 Carbon footprint in rural and urban areas

(Quantification of CO₂ savings due to the actions performed in the pharmacies, considering the travel avoided by patients to their reference health centre)

Area	CO ₂ factor	Non-referred cases	Referred cases	Km savings	CO ₂ (kg) savings	Daily CO ₂ savings (kg)
Urban	0.0620091	182	62	480.42	29.79	
Rural	0.1899847	163	27	5.473.62	1039.90	
Total		345	89	5954.04	1069.69	53.48

capillary blood glucose, four of them did not sign the informed consent and another six, for unknown reasons were not tested either (Table 3).

Capillary blood glucose results

For participants with a Findrisc test result above 15 points, basal capillary blood glucose was determined for 125 participants (10 losses) with a mean result of 124.5 mg/dL (SD=33.6). Of the blood glucose tests performed 71.2% led to results higher than 110 mg/dL and were referred to their primary care doctor for other tests, and as appropriate, confirm the diagnosis.

Referral results

Of the total patients referred to the physician (n=89), 41 returned to the pharmacy to be notified about the results (42.3%); for 13 of them (14.6% of the participants referred) the diabetes diagnosis was confirmed, and pharmacological treatment was established (Table 4). If we consider the total number of participants (n=434), the new patients diagnosed with diabetes represents 3% of the analysed sample.

Environmental impact

The CO₂ emissions saved during the 20 days that the campaign lasted are listed in Table 5.

DISCUSSION

With this study, in addition to being able to detect a considerable number of patients with high or very high risk of suffering from DM2, we can determine that the pharmacy is a good undiagnosed DM2 screening point, which informs the susceptible population about the complications that might arise if the early stage of the disease is not controlled. Moreover, patients are taught guidelines and advice in terms of both nutritional and physical activity to delay its onset (Annex). The number of patients analysed (434 in 20 calendar days, 14 working days) shows the interest of users in performing this type of activity in community pharmacies.

The characteristics of the sample are similar to those found in two previous studies (21,22). In our case 80% of participants were over 45 years old, compared to 75% of the other studies (21,22). Approximately 60% of our participants were women, which coincides with the data obtained in the two studies mentioned, 60%–65% of their sample. In regard to risk factors for the onset of diabetes, more than 75% of our sample presents BMI over 25; the same percentage was obtained in reference studies. Regarding waist circumference, 85% of our participants have values over normal and somewhat higher than those of the other two studies: 75% in both.

The figures for high or very high risk of developing diabetes obtained in this study were 23%, similar to those of previous studies (21, 22). This risk level is reflected above all in participants as of the age of 55 or in those with BMI above 25 kg/m², which reveals that DM2 is a pathology associated with age and affected by risk factors such as overweight or obesity.

The new diagnoses obtained with our study were 3%. This value is similar to another previous study (23), even though the latter has a larger sample.

Focusing on the environmental impact, the data obtained during the 20 days in which the study was performed, extrapolating to a whole year, the atmospheric emissions saved stands at 19,509.23 kg of CO₂. To get a more graphic idea, the saving during those 20 days would be equivalent to:

- The emission produced by a person who travels a 8 km return trip to work by car daily for an entire year.
- The emission produced by 8 people who travel a 3 km return trip from the centre of Valladolid to their homes for a whole year by bus.
- The emission produced by a person who performs a Valladolid–Madrid return trip by train for 6 months daily including Saturdays and Sundays.

An important limitation that we have, has been the return of information received from patients referred to the physician. At this point we included both patients who returned after commencing pharmacological treatment or diet and physical activity patterns, as well as those called by the physician for subsequent analysis and monitoring of blood glucose levels. Of the total patients referred in urban areas the information that came back after the recommendation to request an appointment with their physician did not attain 30%. However, in rural areas these figures are very different, since 85.2% of patients went to the pharmacy to report the results of the consultation. These figures show the degree of trust in rural pharmacists and the greater connection between health professionals, aspects far removed in the city where patients can be passing through or not have a fixed pharmacy to visit.

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Annex. Infographic provided to patients about DM2, its complications, habits and nutritional and physical activity advice to try to delay its onset

Diabetes *mellitus* tipo 2

¿Qué es?

La *diabetes mellitus* (DM) es una enfermedad en la que se produce un aumento en el nivel de azúcar (glucosa) en la sangre. Este aumento se puede deber, bien a una falta de **insulina**, la hormona encargada de retirar el azúcar de la sangre, o bien a que el cuerpo no puede usar correctamente esta insulina.

Existen varios tipos de DM, la más habitual es la llamada DM tipo 2 (DM2).

Síntomas

En muchas ocasiones, sobre todo al principio, los síntomas de la DM2 pueden pasar desapercibidos.

Estos son los síntomas más característicos:

- Aumento de la sed, del apetito y de la necesidad de orinar
- Cansancio y cambios bruscos de humor
- Hormigueo o adormecimiento de manos o pies
- Visión borrosa
- Heridas que tardan en cicatrizar
- Infecciones frecuentes

Si tienes alguno de estos síntomas, coméntaselo a tu profesional sanitario de referencia (médico, enfermera, farmacéutico)

Si además tienes otros factores de riesgo como sobrepeso, hipertensión arterial, colesterol alto, antecedentes de familiares con diabetes, has tenido diabetes durante el embarazo, tienes más de 45 años y no realizas ejercicio de forma habitual, es importante que lo comuniques en tu centro de salud o farmacia.

Diagnóstico

Para saber si tienes diabetes, en tu centro de salud te realizarán un análisis para ver tu glucemia, es decir, tus niveles de azúcar en la sangre.

- En ayunas (al menos 8 horas): niveles mayores a 126 mg/dl
- Al azar (si presentas alguno de los síntomas de diabetes): niveles mayores a 200 mg/dl

Podrían hacerte otras pruebas, como medir la cantidad de azúcar unida a tus glóbulos rojos (HbA1c) o medir la glucemia en ayunas 2 horas después de haber tomado una bebida dulce especial (sobrecarga oral de glucosa).

- HbA1c: valores por encima del 6,5%
- 2 horas después de sobrecarga oral de glucosa: niveles mayores a 200 mg/dl

Con la colaboración de:

Federación Española de Diabetes

Boehringer Ingelheim

Farmacéuticos
Consejo General de Colegios Farmacéuticos


Diabetes mellitus tipo 2

¿Y ahora qué?

Tras el diagnóstico de DM2, se establecerá un plan de tratamiento individual para conseguir controlar tanto los niveles de azúcar en sangre como los factores de riesgo y así evitar que la enfermedad avance o que aparezcan complicaciones.

Educación terapéutica

Desde el momento de tu diagnóstico, tu médico, enfermera y farmacéutico te darán información y conocimientos para manejar la enfermedad y mejorar tu calidad de vida. Te harán recomendaciones sobre alimentación, ejercicio físico, consumo de alcohol o tabaco, pérdida de peso, cuidados personales, uso de medicamentos, etc.




Modificaciones del estilo de vida

Llevar una **alimentación saludable** y practicar **ejercicio físico** son fundamentales para controlar la glucemia y retrasar la aparición de complicaciones.


<h4>Alimentación</h4> <p>Sigue una dieta mediterránea donde no falten:</p> <ul style="list-style-type: none"> • Frutas, verduras, legumbres y cereales integrales • Lácteos desnatados • Aceite de oliva • Pescado, carnes magras y huevos • Frutos secos • Agua <p>Evita tomar:</p> <ul style="list-style-type: none"> • Alcohol • Refrescos con azúcar • Alimentos precocinados, bollería industrial, embutidos. 	<h4>Ejercicio físico</h4> <p>Practica ejercicio físico moderado, de forma regular y durante al menos 30 minutos al día. Elige un tipo de ejercicio que te guste y motive (caminar, nadar, bicicleta, bailar, yoga, etc.).</p> <p>Si vas a practicar ejercicio durante un tiempo prolongado, toma algún alimento rico en azúcar, por ejemplo una pieza de fruta, antes de empezar.</p>
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Tratamiento farmacológico

Puede que al principio, con dieta y ejercicio sea suficiente para controlar la DM2, pero pasado un tiempo, el médico puede añadir algún medicamento antidiabético.



Tu profesional sanitario de referencia resolverá todas tus dudas sobre: para qué es el medicamento, cuánto tienes que tomar, cómo tienes que tomarlo o durante cuánto tiempo, cómo tienes que conservarlo o qué hacer si experimentas algún tipo de problema cuando empieces a utilizarlo.




Complicaciones


Pueden ser problemas puntuales, como una bajada de azúcar (hipoglucemia) o una subida (hiperglucemia) o problemas que se desarrollan a lo largo del tiempo afectando a distintas partes del cuerpo.

- **Hipoglucemia:** una bajada de azúcar provoca temblores, sudoración, mareo, visión borrosa o confusión. Puede producirse por haber estado demasiado tiempo en ayunas, haber realizado mucho ejercicio o también puede ser efecto de algunos medicamentos antidiabéticos.
- **Hiperglucemia:** las subidas de azúcar pueden deberse a una deshidratación, el uso de corticoides, infecciones o por no tomar la medicación antidiabética.
- **Neuropatía diabética:** es una pérdida de sensibilidad, tacto y en algunos casos dolor, principalmente en las extremidades y se produce porque las terminaciones nerviosas están dañadas.
- **Nefropatía diabética:** es una alteración a nivel de los riñones que, si no se controla, puede producir problemas en su funcionamiento.
- **Retinopatía diabética:** la retina del ojo se ve afectada y puede evolucionar hasta la ceguera.
- **Enfermedades cardiovasculares:** la DM2 se asocia a una mayor prevalencia de Infarto agudo de miocardio, ictus e insuficiencia cardíaca.


Pie diabético



Revisa cada día tus pies después del baño o ducha para comprobar que no haya ninguna herida o ampolla, cambios en el color de la piel o zonas inflamadas. Seca bien los pies después del baño o ducha y aplica crema hidratante.



Córtate las uñas rectas usando un cortaúñas o lima. No utilices callícidas, cuchillas o piedra pómez para quitar durezas. Ve a tu podólogo.



Usa zapatos cómodos, flexibles y transpirables que no aprieten el pie y calcetines de algodón sin costuras prominentes.