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2021-08

Gabriel , R , Acosta , T , Florez , K , Anillo , L , Navarro , E , Boukichou , N , Acosta-Reyes , J , Barengo , N C , Lindstrom , J , Tuomilehto , J O & Aschner , P 2021 , ' Validation of the Finnish Type 2 Diabetes Risk Score (FINDRISC) with the OGTT in Health Care Practices in Europe ' , Diabetes Research and Clinical Practice , vol. 178 , 108976 . <https://doi.org/10.1016/j.diabres.2021.108976>

<http://hdl.handle.net/10138/346542>

<https://doi.org/10.1016/j.diabres.2021.108976>

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Contents available at [ScienceDirect](https://www.sciencedirect.com)

Diabetes Research
and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres



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Validation of the Finnish Type 2 Diabetes Risk Score (FINDRISC) with the OGTT in Health Care Practices in Europe



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ARTICLE INFO

Article history:

Received 27 April 2021

Received in revised form
28 June 2021

Accepted 19 July 2021

Available online 22 July 2021

Keywords:

Diabetes

FINDRISC

Glucose impairment

OGTT

Community and opportunistic
screening

Primary care settings

ABSTRACT

Aims: /hypothesis.

To determine the best cut-off threshold value of the Finnish Diabetes Risk Score (FINDRISC) for the detection of diabetes and non-diabetic hyperglycaemia in people 35 years or older at primary health care settings in Europe.

Methods: Cross-sectional study in 11,444 adults from primary health care centres using community and opportunistic screening approaches. All participants completed the FINDRISC questionnaire and underwent a 2-hour oral glucose tolerance test (OGTT). The FINDRISC performance was assessed by the area under the curve (AUC) using receiver operating characteristics (ROC) analysis. The sensitivity, specificity, Youden's index, positive and negative prediction values for different FINDRISC cut-offs were calculated.

Results: The optimal FINDRISC value for detecting both diabetes or glucose impairment in the community - screened sample was 14 point with the associated AUC 0.75,5 (95 %CI 0.73,7–0.77,3). The optimal score in the opportunistic screening sample was 16 with the associated AUC only 0.60,4 (95% CI 0.56, 4–0.64, 4).

Conclusions/interpretation: The FINDRISC is a non-invasive tool useful for detecting people with unknown diabetes and glucose impairment in people visiting primary health centres in Europe.

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<https://doi.org/10.1016/j.diabres.2021.108976>

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1. Introduction

The main risk factors for type 2 diabetes (T2D) are overweight and obesity, sedentary lifestyle, unhealthy diet, intermediate non-diabetic hyperglycaemia, hypertension, dyslipidaemia, aging, family history of diabetes, low birth weight, and gestational diabetes in women [1].

Systematic measurement of fasting plasma glucose (FPG) in the general population is widely questioned as a screening tool to detect previously unknown T2D due to its high variability and low efficacy [2]. Although a non-laboratory diabetes risk score will not overcome the difficulty of measuring glycaemia at the population level, it will help to select people with high probability of having any glucose abnormality, i.e. impaired glucose tolerance (IGT), impaired-fasting glucose (IFG) or diabetes, and therefore having a need for a glycaemia testing to confirm or discard such an abnormality.

Lindström et al developed, a non-invasive risk score, the Finnish Diabetes Risk Score (FINDRISC), which does not require any laboratory measurements, to estimate the individual risk of developing diabetes [3,4]. Although the FINDRISC score was primarily designed to determine the risk of developing diabetes in 10 years, it has been also used to identify people with possible undiagnosed diabetes or non-diabetic hyperglycaemia prior to the confirmatory glycaemia testing. In the Finnish population, the most efficient cut-off to discriminate between high and low risk of having diabetes was 14/15 points [4]. Since the FINDRISC is non-invasive, low cost, and easy to perform with a good sensitivity and specificity, it has been translated into several languages, and culturally adapted to various populations all over the world [5,6].

A recent systematic review with a meta-analysis conducted by our group (data not published yet) found the efficacy and precision of the FINDRISC is associated with a high variability among different ethnic groups and geographic locations for the detection of unknown diabetes. The significant heterogeneity observed around the world and the low-to-moderate quality of identified studies pointed out the importance to formally validate the FINDRISC score for specific populations, in order to improve its precision. We previously reported preliminary descriptive data on the distribution of the FINDRISC score in a selected subsample of Diabetes--Prevention Using Lifestyle, Physical Activity and Nutritional Intervention (DE-PLAN) participants [7]. The main objective of this analysis was to determine the best FINDRISC threshold for the detection of diabetes and non-diabetic hyperglycaemia in people aged 35 years or older at primary health care settings across Europe.

2. Methods

2.1. Study design and population

Briefly, the first phase of the DE-PLAN project was a cross-sectional screening in which several primary healthcare practices throughout Europe with expertise in cardio-metabolic

and diabetes assessment were included [8]. Participating centers were located in Austria, Bulgaria, Finland, Greece, Italy, Lithuania, Norway, Poland, Serbia, Spain and the UK (Table 1-S), and used different screening approaches: i.e. non-selective community screening and opportunistic screening of outpatient individuals attending these clinics. Recruitment of participants was done in 2010.

Participants were not eligible for the study if they had known or treated diabetes, previous history of CVD, could not provide informed consent, had a terminal illness, or could not visit the clinic. Local investigators were trained on how to administrate the FINDRISC questionnaire and how to perform the OGTT. After obtaining written consent, the local investigators collected information on personal medical history, lifestyle and performed the two tests.

2.2. Measurements

The FINDRISC is composed of eight categorized items: age, body mass index (BMI), waist circumference, personal history of high glucose, family history of diabetes, antihypertensive medication use, daily consumption of fruits and vegetables, and daily physical activity. The total possible score ranges from 0 to 26. All participants who completed the FINDRISC were invited to undergo the OGTT, regardless of the FINDRISC result. In those accepting, a standard 2-hour OGTT with a 75 g oral glucose load, was done. Both fasting (FPG) and 2-hour post-challenge (2hPG) plasma glucose was measured. We used the WHO criteria for glucose classification [9].

2.3. Statistical analysis

Frequency distributions of the FINDRISC components are presented in absolute numbers and percentages. The Chi-square test was used to evaluate whether there were statistical differences in the proportions between subgroups. The performance of the screening test was evaluated by means of the analysis of Receiver Operating Characteristic (ROC) curve, using the OGTT results as the classification variable (gold standard). The area under the curve (AUC) was used to calculate the ability of the FINDRISC to detect unknown diabetes or non-diabetic hyperglycaemia. The internal validity indexes (sensitivity, specificity and Youden's index), and external validity indexes of the FINDRISC (positive and negative predictive values) with their respective 95% confidence intervals (95% CI) were also calculated. In addition, the optimal cut-off point to define the threshold of the high-risk and low-risk populations was calculated. The prevalence of diabetes risk according to FINDRISC scoring and the OGTT results are shown by sex and age group. Statistical significance was considered when p -value < 0.05 . The data processing and analysis was carried out with the statistical software R version 4.0.0.

2.4. Ethical considerations

The study was approved by the local ethic committee of all participating centers. All participants received exhaustive

information about the study, including the explanation of the right to withdraw their participation. All participants signed the written informed consent. All centers followed the European Good Clinical Practice Guidelines and the Declaration of Helsinki as revised in 2008. The DE-PLAN project was registered in Clinical Trials Gov. Identifier: NCT01365013

3. Results

In the DE-PLAN several thousands of FINDRISC questionnaires were distributed in the participating European centres. The present analysis includes 11,444 participants, 35–74 years old (5,842 women; 51%), with both FINDRISC and OGTT complete data from 11 participating centers that transferred all requested data to the Coordinating Centre in Madrid, Spain. Six countries using community screening (Austria, Finland, Greece, Italy, Lithuania and the UK) recruited 9,730 individuals (85% of the total sample). The other five centers (Bulgaria, Norway, Poland, Serbia and Spain) used opportunistic screening, and recruited 1,714 individuals (see supplemental Table 1-S for more detail).

Table 1 shows the prevalence of each FINDRISC component in the total population and by sex. Forty percent of the participants were between 55 and 64 years old, and 51% were women. Most participants (68.9%) reported daily consumption of fruits and vegetables, higher in women than men, and 55.6% of participants reported physical activity of at least 30 min per day, similar in both sexes. The percentage of par-

ticipants receiving treatment for hypertension was 39.8%, and 20.4% reported a prior high glucose level, more frequently among women. Only 22.1% of the study population had a normal body mass index (BMI) and 76.9% of women were overweight or obese. Family history of diabetes (first or second degree) was more prevalent in women than in men.

Table 2 shows that 30.7% of total participants (33.7% in men) had abnormal glucose tolerance/glucose impairment (choose either of these two options) and 8.6% (10.3% of men) unknown isolated T2D according to OGTT. The prevalence of HRD (FINDRISC score > 14) was higher in women compared to men (46.6% vs 36.2% respectively). All HDR, glucose impairment and T2D increased with age ($p < 0.001$), with highest figures in the oldest age group.

Fig. 1 shows separate ROC curves for detection of previously undiagnosed diabetes and non-diabetic hyperglycaemia in the community-screened sample. The AUC for non-diabetic hyperglycaemia was 67.3 (95% CI 66.2–68.3) while for the detection of diabetes it was 74.4 (95% CI 72.9–76.0). The best threshold for detecting both conditions was 14 FINDRISC points.

In the high-risk screened sample, the AUC for detecting glucose alteration (non-diabetic hyperglycaemia) was 59.6 (95% CI 56.9–62.3), and for the detection of unknown diabetes 60.4 (95% CI 56.4–64.4). The best cut-offs in the high-risk sample was 15 for the detection of non-diabetic hyperglycaemia, and 17 for unknown diabetes.

Table 1 – Frequency of the components of the FINDRISC by sex.

FINDRISC Item	Sex		Total (n = 11444)
	Male (n = 5,602)	Female (n = 5,842)	
Age (years)			
<45	451 (8,0)	475 (8,1)	926 (8,1)
45–54	1579 (28,2)	1505 (25,8)	3084 (26,9)
55–64	2221 (39,6)	2377 (40,7)	4598 (40,1)
>64	1351 (24,1)	1485 (25,4)	2836 (24,8)
BMI (kg/m ²)			
<25	1182 (21,1)	1347 (23,1)	2529 (22,1)
25–30	2803 (50,0)	2342 (40,1)	5145 (45,0)
>30	1617 (28,9)	2153 (36,8)	3770 (32,9)
Waist circumference (cm)			
Men < 94; Women < 80	1607 (28,7)	856 (14,6)	2463 (21,5)
Men 94–102; Women 80–88	1917 (34,2)	1512 (25,9)	3429 (30,0)
Men > 102; Women > 88	2078 (37,1)	3474 (59,5)	5552 (48,5)
Physical activity (>30 min/day)			
Yes	3114 (55,6)	3257 (55,8)	6371 (55,6)
Vegetables/fruit daily consumption			
Yes	3682 (65,7)	4209 (72,0)	7891 (68,9)
Drug treatment for hypertension			
Yes	2139 (38,2)	2418 (41,4)	4557 (39,8)
Previous history of high blood glucose			
Yes	1048 (18,7)	1286 (22,0)	2334 (20,4)
Family history of diabetes			
Yes, first degree	1494 (26,7)	1920 (32,9)	3414 (29,8)
Yes, second degree	1898 (33,9)	1827 (31,3)	3725 (32,5)
No	2210 (39,5)	2095 (35,9)	4305 (37,6)

Data presented as n (%). BMI, body mass index.

Table 2 – The probability of T2D in the OGTT according to the FINDRISC value, sex and age.

Variable	Total (n = 11444)	Prevalence by sex		P-value*	Prevalence by age-group			P-value*	
		Men (n = 5602)	Women (n = 5842)		< 45 years (n = 926)	45–54 years (n = 3084)	45–54 years (n = 4598)		> 64 years (n = 2836)
FINDRISC value									
FINDRISC < 14	6693 (58.5)	3572 (63.8)	3121 (53.4)	< 0.001	734 (79.3)	2045 (66.3)	2710 (58.9)	1204 (42.5)	
(FINDRISC ≥ 14)	4751 (41.5)	2030 (36.2)	2721 (46.6)		192 (20.7)	1039 (33.7)	1888 (41.1)	1632 (57.5)	
OGTT Results									
NGT	7932 (69.3)	3715 (66.3)	4217 (72.2)	< 0.001	787 (85.0)	2325 (75.4)	3118 (67.8)	1702 (60.0)	
i IFG	848 (7.4)	551 (9.8)	297 (5.1)		14 (1.5)	224 (7.3)	400 (8.7)	210 (7.4)	
i IGT	1150 (10.0)	485 (8.7)	665 (11.4)		79 (8.5)	244 (7.9)	447 (9.7)	380 (13.4)	
IGT + IFG	534 (4.7)	273 (4.9)	261 (4.5)		18 (1.9)	92 (3.0)	232 (5.0)	192 (6.8)	
TD2	980 (8.6)	578 (10.3)	402 (6.9)		28 (3.0)	199 (6.5)	401 (8.7)	352 (12.4)	

* NGT, Normal Glucose Tolerance; iIFG: isolated impaired fasting glycaemia; iIGT: isolated impaired glucose tolerance; T2D, type 2 diabetes.

Fig. 1-S shows the AUC for the detection of non-diabetic hyperglycaemia and diabetes in both sample (community-screened sample, and high-risk sample).

Table 1-S shows the total numbers and percentages of high-risk-diabetes (HRD) and low-risk -diabetes (LRD) according to FINDRISC by country and screening method used. In total, 4,751 individuals (41, 5%) were classified as HRD (FR ≥ 14) and the rest (6,693 individuals; 58, 5%) as LRD (FR < 14).

Table 2-S shows the variation in the OR and the Youden's index in the detection of glucose alterations and diabetes, for each cut-off point considered. In the community-based screening sample, a FINDRISC value of 14 points reached the highest Youdens index (best fit) for both the detection of non-diabetic hyperglycaemia was (25.3) and for diabetes (36.6). For non-diabetic hyperglycaemia the sensitivity was 59.1 (95 %CI 57.4–60.7) and specificity 66.2 (95% CI 65.2–67.3). For screen-detected diabetes the sensitivity and specificity were 70.5 (95% CI, 67.5–73.3) and 66.2 (95% CI, 65.2–67.3) respectively. Fifty eight percent (6,693 individuals) of the total sample showed a FINDRISC score < 14 (low risk) and 21.4% of them had non-diabetic hyperglycaemia or T2D in the OGTT. Thus, the probability that an individual with a FINDRISC < 14 points had NGT was 78.5%, while in the high-risk group (FINDRISC ≥ 14), the probability of having NGT was 56.3%.

Table 3-S displays additional information regarding the mean age, the percentage of males/females, percentage of glycaemia alteration during the OGTT, the median FINDRISC score, and the cut-off values for glucose alteration and T2D by country.

4. Discussion

The ROC analyses shown that the FINDRISC score worked better in the community-screened group, with the optimal cut-off of 14 for both detecting unknown diabetes and glucose impairment. There is some concern about the Youden's index, because it assumes that the risk of false negative and false positive are equivalent (i.e. specificity and sensitivity assumed to be equally important). For a screening test sensitivity may be more important than specificity. Therefore the cut-off may be better when sensitivity is better than specificity (sometimes the Youden's index favors specificity). Given the good sensitivity and specificity observed, we consider the cut-off 14 is a reasonable threshold to rule out unknown diabetes and glucose impairment in the European adult community. In the opportunistic-screened group, however the threshold were higher for glucose impairment (15 points) and for known diabetes (17 points).

The study sample is large enough and includes several primary care practices in different European countries. The inclusion of different methods of screening (community -based and opportunistic) is another important strength, allowing the possibility to assess the efficacy of different screening strategies. The FINDRISC score is a short questionnaire easy and cheap to apply in busy medical practices, which requires very little time to complete it. Therefore, the FINDRISC score could be helpful to rule out diabetes and glucose impairment in the first place at primary care settings.

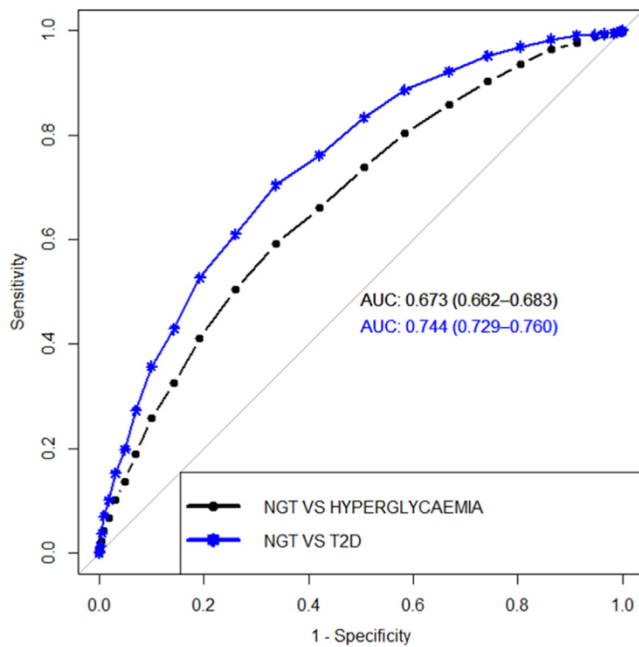


Fig. 1 – AUC for detection of any glucose impairment or unknown diabetes with the FINDRISC compared to OGTT in the community-based screening sample.

However, the study has some limitations as the potential selection bias, particularly in the high-risk opportunistic screening group. Recall bias is also a limitation of any screening questionnaire, particularly in those individuals with family history of diabetes or previous measured elevated glucose, since these people usually report healthier lifestyles has higher consumption of fruits and vegetables, and more physical activity.

The 85% of the sample (9,730 individuals) was recruited mainly from primary care practices, where the expected prevalence of HRD is higher than in the general population. This might have introduced some selection bias. Also, 30% of participants who completed the FINDRISC score rejected the OGTT, mainly they did not accept to stay more than 2 h at the clinic. Therefore, healthier individuals might have missed the OGTT.

Several screening studies of diabetes and prediabetes have been conducted all over the world, including Caucasian, Black, Asian and Hispanic ethnic groups. For instance, the FINDRISC was applied in the United States to different ethnic groups of the general population [10]. The AUC for the detection of unknown diabetes was 0.75, and 0.67 for prediabetes. The best cut-off point for diabetes was 11 in White-Caucasian (sensitivity 74.93%) and Hispanic individuals (sensitivity 65.98%), and 12 for African-Americans (sensitivity 71.25%). For prediabetes, the best cut-off was 10 for all three ethnic groups, but with higher sensitivity in whites (62.42%) and the lowest in Hispanics (55.88%). The AUC for diabetes and prediabetes were similar to our study (0.75 for diabetes, 0.67 for prediabetes).

Another study compared FINDRISC results between Indians living in India and migrant Indians in the UK [11]. For a cut-off point of 21, the sensitivity was higher for the Indian migrants, but the specificity was lower. This was attributed to

a higher prevalence of risk factors in the group of migrants. The study questioned the generalization of the same cut-off for all individuals of the same ethnic group but living in different countries or cultures.

In Latin American population, a similar study conducted recently in Peru [12], obtained an AUC of 0.73 (95% CI 0.65–0.78) for unknown diabetes. These results are also quite similar to our study for the detection of unknown diabetes.

Finally, a recent systematic review [13] found up to 400 candidates studies conducted all over the world on the issue, some of them in Europe, but few of them were qualified for meta-analysis. Several FINDRISC cut-offs (from 9 to 15) were assessed in this systematic review. The AUC varied between 0.669 and 0.804, with an average sensitivity of 53, 7%, (95% CI 0.410–0.660), specificity of 82, 6% 95% CI 0.653–0.923), and false positive rate ranging between 23.8% and 46, 4%. The cut-off of 12, although with lower sensitivity, reduced significantly the rate of false positives, increasing specificity with moderate evidence quality. This systematic review pointed out that the majority of published studies are small and of low-moderate quality according to the GRADE system. So far, we are not aware about any FINDRISC formal validation for the Caucasian European population.

Detection of unknown diabetes and prediabetes in primary care is of high public health relevance for the early implementation of preventive and health care programs aimed to reduce the risk and manage modifiable risk factors through lifestyle modification. In this study, we found sex differences in the prevalence of all FINDRISC components, except for the physical activity. Likewise, significant differences by the type of screening, except for the consumption of fruits and vegetables, was observed. The higher cutoff obtained with opportunistic screening may be explained because in opportunistic screening the individuals were “pre-filtered” by higher risk. This screening program can contribute to reduce the burden of diabetes complications and public health impact of the disease in the health system. However, we recognize the limitation of the FINDRISC score alone for the detection of glucose alterations and unknown diabetes with small AUC of 0.673 and 0.744, respectively.

The FINDRISC score is an adequate and useful non-invasive test for the screening of diabetes in the primary care setting, allowing in the first place the detection of people with HRD, and leaving the performance of an OGTT only for these individuals in a second step. Therefore, we recommend the OGTT when the FINDRISC score is higher than 14 in HRD European individuals. However, the cost-effectiveness of this strategy need to be confirmed in large studies within the European public health systems.

However, new prospective studies are needed to confirm the usefulness in predicting diabetes of this score in healthy people, as well to estimate the cost-effectiveness of this strategy at the population level within the European public health systems [14].

Funding

The DE-PLAN project was funded by the European Commission. General Directorate SANCO (Grant Agreement: 2004310).

The study sponsor/funder was not involved in the design of the study; the collection, analysis, and interpretation of data; writing the report; and did not impose any restrictions regarding the publication of the report.'

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

Co-coordinating centres:

- University of Helsinki, Helsinki, Finland. Prof. Jaakko Tuomilehto Dr. Noel Barengo, Dr Jaana Lindström.

- Finnish Institute for Health and Welfare, Helsinki, Finland Dr. Markku Peltonen.

- Madrid: World Community for Prevention of Diabetes (WCPD) Foundation. Gabriel R. Tuomilehto J.

Clinical centres:

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- Bulgaria. Sofia: University Hospital "Alexandrov" Clinic of Endocrinology. Prof. Vladimir Christov, Dr. Zdravko Kamenov.

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- Norway. Verdal: Norwegian University of Science and Technology. Dr. Kristian Midthjell.

- Poland. Krakow: Jagiellonian University Medical Colleg. Prof. Zbigniew Szybinski Dr. Aleksandra Gilis Januszewsk.

- Serbia. Belgrad: Institut for Endocrinology, Diabetes, and Metabolic Diseases, Prof. Predrag Jordjevic.

- Spain. Madrid: Instituto IDIPAZ, Hospital Universitario La Paz, Madrid: Prof. Rafael Gabriel, Dr. Esther Sanchez. SERMAS-Madrid: Dr. Blanca Novella, Dr. Belén Sierra, Dr JC Abanades, Ms. Rosa Arnal; SACYL-Castilla-León: Dr Saturio Vega, Dr. Almudena Cantalejo, Ms. Pilar Marques, Dr Aurora Fernández, Dr. Luis Gonzalves, Dr. Maria Sol Fragüas, Dr. José María Pinilla; SESCAM- Castilla-La Mancha: Dr. Jaime Aranda, Ms Alba del Hoyo, Mr. Luis Sánchez, Dr. Laura Ruiz.

- U.K. Leicester: University Hospitals of Leicester NHS Trust. Dr. Melanie Davies, Dr. Kampesh Khuntí, Dr. Stephen Hiles, Ms. Jacqui Throughton.

Data availability.

The full protocol of the study, the final report submitted to the DG-SANCO, the database and the statistical outputs reported in the article are free available upon request by

email to the Asociación Española de Investigación en Prevención de Diabetes and Cardiovascular Diseases (PREDICOR) c/General Pardiñas 64, Madrid 28001, Spain: rgabriel@ceiis.org.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2021.108976>.

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