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Rethinking the accuracy of 75 g glucose used in the oral glucose tolerance test in the diagnosis and management of diabetes



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ABSTRACT

Aims: We investigated the specificity of the 75 g oral glucose tolerance test (OGTT) and the clinical usefulness of the 2 h post loading glucose (2 h PLG) value in the clinical care of diabetes patients.

Methods: The 75 g OGTT data of 1755 subjects were analyzed. The relationships and degrees of consistency among 2 h PLG, fasting plasma glucose (FPG), and HbA1c values were assessed. We also investigated the degree of contribution of 2 h PLG in the prescription of glucose-lowering agents and in the pitfall group for use of 75 g OGTT.

Results: Among 595 subjects with normal FPG, only 329 (55.3%) showed normal 2 h PLG level, and 66 (11.1%) patients could be considered as having diabetes. Among 454 diabetes patients (based on FPG and HbA1c), 409 (90.1%) showed 2 h PLG values in the range of diabetes, 45 (9.9%) subjects did not exhibit diabetes. Pitfall group who used 75 g OGTT for diagnosis diabetes (lower 2 h PLG value compared to fasting and upper 2 h PLG value compared to fasting) showed differences in body weight and height.

Conclusions: Based on OGTT results, around 10% patients cannot be diagnosed with diabetes based solely on the 2 h PLG value. Further studies on differences in glucose loading according to body weight, individual life pattern, and calorie requirement are needed for improvement of the specificity of the OGTT in the clinical management of diabetes.

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1. Introduction

The diagnosis of diabetes is based on the American Diabetes Association (ADA) criteria using fasting plasma glucose (FPG), random glucose higher than 11.1 mmol/L with typical symp-

toms, HbA1c value, and the 75 g oral glucose tolerance test (OGTT) [1]. Among these diagnostic tools, the 75 g OGTT is very useful in under diagnosed patients with the pre-diabetic condition of impaired fasting glucose (IFG) [2]. However, some patients previously diagnosed with diabetes based on the 75 g OGTT in hospital have shown glucose values within normal

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or pre-diabetes range in self-monitoring blood glucose (SMBG) records in routine daily life. Such patients do not need anti-diabetes medication, and life style modification is the initial management strategy of choice. However, the possibility that these patients might be over-diagnosed with diabetes due to the relatively high glucose dose of 75 g in the OGTT should not be overlooked. This situation might be common in clinical practice. The 75 g OGTT is well known to be helpful for the diagnosis of diabetes, especially when patients show an IFG state; however, it is not clear why a 75 g dose of glucose is used and whether this amount is adequate for every IFG patient. In addition, inter- or intra-individual variability and low reproducibility can be pitfalls in the 75 g OGTT. The amount of glucose loading might need to be individualized according to body weight, height, daily caloric intake, and race, if necessary, although 75 g is well accepted as a standard glucose dose in the OGTT.

Therefore, we need to reconsider whether 75 g glucose load is appropriate irrespective of patient clinical characteristics. The relationship between glucose value and 75 g OGTT and its clinical significance should also be considered in the clinical care of high-risk patients with diabetes with regard to medication initiation and avoidance of unnecessary medication. Micro-vascular complications such as diabetic autonomic neuropathies can also impact the glucose level, resulting in a lack of response despite the loaded glucose amount [3]. However, the glucose response from a 75 g glucose load is expected to differ according to variable patient factors such as beta cell function, enteric hormones, and neural responses to nutrient ingestion. For example, the results might differ between a 50 kg patient and a 100 kg patient, even if they have similar pancreatic beta cell function or insulin resistance. Therefore, low-body weight patients might be diagnosed with diabetes, even though routine daily glucose values do not exceed the diabetes threshold. On the contrary, high-body weight patients might not show glucose values indicating diabetes, even though routine daily glucose values are in the diabetic range, because 75 g is too small of a dose to increase the glucose level to 11.1 mmol/L compared to the routine daily caloric intake needed to maintain their body mass index (BMI).

In this study, we investigated the rate of diagnosis of diabetes based on the 75 g OGTT compared to that based on the FPG and HbA1c. Furthermore, we analyzed the usefulness of 75 g OGTT results in the decision to prescribe anti-diabetes medication in clinical practice. We also assessed the characteristics of the pitfall group in the use 75 g OGTT, which could be under-diagnosed or over-diagnosed with diabetes using a 75 g glucose load compared to FBS, HbA1c, and SMBG results based on routine daily caloric intake.

2. Methods

Total 2810 patients had 75 g OGTT in Chonbuk National University Hospital, Korea from 1995 to 2013. And there was already an informed consent of permission for using patient's OGTT data in the future for study at that time. Based on these consents, we received the approval of Institutional Review Board of Choubuk national university hospital (Reg. No. 2016-

05-030-001). 270 patients were excluded due to malignancy, anemia, chronic kidney disease or other disease. Therefore, OGTT results of total 1755 patients were analyzed in this study. We performed a retrospective analysis of 75 g OGTT data in 1755 patients. We evaluated history of disease, family history, and medications using medical records. We also assessed body weight, height, BMI, and all laboratory findings, including HbA1c, 75 g OGTT glucose level, fasting insulin, and c-peptide level.

Diagnoses of diabetes, pre-diabetes, and normal glucose state were defined based on the ADA guidelines follows [4] normal, FPG <5.6 mmol/L; impaired fasting glucose, 5.6 mmol/L ≤ FPG <7.0 mmol/L; and diabetes, FPG ≥ 7.0 mmol/L. 2 h post loading glucose (PLG) after 75 g OGTT <7.8 mmol/L indicated a normal state, 7.8 mmol/L ≤ 2 h PLG <11.1 mmol/L indicated impaired glucose tolerance, and 2 h PLG ≥ 11.1 mmol/L indicated the presence of diabetes. Among 1755 patients, 595 patients (33.9%) showed normal FPG (below 5.6 mmol/L), however, they had high risk factors of diabetes such as 40 years old, family history of diabetes, overweight, hypertension, dyslipidemia, or cardiovascular disease [4] or showed 7.8-11.1 mmol/L range of random glucose value. FPG of 706 patients (40.2%) were between 5.6 and 7.0 mmol/L, hence OGTT was performed to diagnosis prediabetes or diabetes exactly. 454 patients (25.9%) already showed FPG over 7.0 mmol/L, however, OGTT also was performed to assess the degree of glucose tolerance. The 75 g OGTT data of 1755 subjects were analyzed to compare the 2 h PLG value after 75 g glucose loading with HbA1c and FPG in the coincidence of diabetes diagnosis to reaffirm the accuracy of the 2 h PLG value in the diagnosis of diabetes. We also reviewed the role of the 2 h glucose value in the decision to initiate glucose-lowering agents in diabetes patients who were diagnosed by 75 g OGTT. Furthermore, we evaluated the clinical characteristics of the pitfall group in the use of 2 h glucose value after 75 g OGTT for the diagnosis of diabetes.

All statistical analyses were performed using the Statistical Package for the Social Sciences 18 (SPSS Inc., Chicago, IL). Data are expressed as mean ± standard deviation (SD) or median (interquartile range [IQR]), and categorical variables are presented as percentage. For comparisons between groups, Student's t test was used for normally distributed variables and the Mann-Whitney U test for variables with skewed distribution. The Spearman correlation method was used for evaluation of significant correlation between variables. We assessed the sensitivity and specificity of each glucose value determined in the 75 g OGTT for diabetes diagnosis and analyzed receiver operating characteristic curves for the diagnosis of diabetes according to 75 g OGTT fasting, 1 h, and 2 h glucose levels, and HbA1c. P values <0.05 were considered statistically significant for all calculations.

3. Results

3.1. Subject characteristics

Baseline subject characteristics are presented in Table 1. The mean age of 1755 subjects was 52.2 ± 12.9 years. Among 1755 patients, the number of subjects less than 30 years old was

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