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Oral glucose tolerance test: unnecessary requests and suitable conditions for the test

Teste oral de tolerância à glicose: solicitações desnecessárias e condições adequadas a realização do teste

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ABSTRACT

Introduction: The oral glucose tolerance test (OGTT) is an important test for diagnosis of diabetes mellitus (DM) that needs criteria to be requested and analytical performance evaluation. **Objectives:** Determine the prevalence of unnecessary OGTT requests and analyze patients' suitability criteria for glucose load. **Method:** Cross-sectional, descriptive and analytical study conducted with 554 patients who had OGTT requested from January to April 2018. Data from laboratory tests were collected through Complab Advanced version 6.9.6 system, organized into a Microsoft® Excel table and analyzed using Epi Info™, version 7.2.1.0. The accuracy of the glucometer paired analysis was performed by determinations of Student's *t* test, using SPSS version of IBM 21™. Patients with a previous diagnosis of DM and/or who showed OGTT request as a screening test along with blood glucose or glycated hemoglobin were classified as unnecessary requests. **Results:** Among the studied patients, 17% (94) had unnecessary OGTT requests, 53 (53.4%) patients had blood glucose ≥ 140 mg/dl and previous DM and/or OGTT used as screening; 41 (43.6 %) patients with capillary blood glucose < 140 mg/dl, but with a diagnosis of DM. The glucometer proved to be accurate with a high correlation ($r^2 = 0.97, p < 0.0001$) with serum glucose. Approaches during screening and capillary blood glucose prevented unnecessary exposure to glucose overload in 67% (63) of the patients. **Conclusion:** The high prevalence of unnecessary OGTT requests underscores the need of criteria for OGTT requesting and the standardization of procedures for screening in the exam.

Key words: glucose tolerance test; diabetes mellitus; unnecessary tests; costs and cost analysis.

RESUMO

Introdução: *O teste oral de tolerância à glicose (TOTG) é um importante exame para diagnóstico do diabetes* mellitus *(DM) que necessita de critérios para solicitação e padronização em sua realização.* ***Objetivos:*** *Determinar a prevalência de solicitações desnecessárias de TOTG e analisar os critérios de aptidão do paciente para sobrecarga glicêmica.* ***Método:*** *Estudo de corte transversal, descritivo e analítico, realizado com 554 pacientes que tiveram TOTG solicitado entre janeiro e abril de 2018. Dados dos exames laboratoriais foram coletados utilizando o sistema Complab Advanced versão 6.9.6, tabulados no Microsoft® Excel e analisados no Epi Info™, versão 7.2.1.0. A acurácia do glicosímetro foi medida por análise pareada das determinações em teste* t *de Student, por meio do IBM SPSS® versão 21™. Pacientes com diagnóstico prévio de DM e/ou que apresentaram solicitação de TOTG como teste de triagem junto com glicemia ou hemoglobina glicada foram classificados como solicitações desnecessárias.* ***Resultados:*** *Dos pacientes estudados, 17% (94) tiveram solicitações desnecessárias de TOTG: 53 (53,4%) com glicemia capilar ≥ 140 mg/dl e DM prévio e/ou TOTG usado como triagem; 41 (43,6%) com glicemia capilar < 140 mg/dl, mas com diagnóstico de DM. O glicosímetro mostrou-se preciso, com elevada correlação ($r^2 = 0,97$, $p < 0,0001$) com a glicemia sérica. As abordagens durante a triagem e a glicemia capilar evitaram a exposição desnecessária à sobrecarga de glicose em 67% (63) dos pacientes.* ***Conclusão:*** *A alta prevalência de solicitações desnecessárias de TOTG ressalta a necessidade de critérios para solicitação do TOTG, bem como a padronização de procedimentos para triagem na realização desse exame.*

Unitermos: *teste de tolerância à glicose; diabetes* mellitus*; exames desnecessários; custos e análise de custo.*

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RESUMEN

Introducción: *La prueba de tolerancia a la glucosa oral (PTGO) es un importante examen para diagnóstico de la diabetes mellitus (DM) que requiere criterios de solicitud y estandarización en su consecución.* ***Objetivos:*** *Establecer la prevalencia de solicitudes innecesarias de PTGO y analizar los criterios de aptitud del paciente para una sobrecarga de glucosa.* ***Método:*** *Estudio de corte transversal, descriptivo y analítico, llevado a cabo con 554 pacientes que tuvieron PTGO solicitado entre enero y abril de 2018. Datos de las pruebas de laboratorio fueron recolectados con el sistema Complab Advanced versión 6.9.6, tabulados en Microsoft® Excel y analizados en Epi Info™, versión 7.2.1.0. La precisión del glucómetro fue medida por análisis pareado de las determinaciones en la prueba* t *de Student, mediante el IBM SPSS® versión 21™. Pacientes con diagnóstico previo de DM y/o que presentaron solicitud de PTGO como prueba de cribado junto con glucemia o hemoglobina glucosilada fueron clasificados como peticiones innecesarias.* ***Resultados:*** *Entre los pacientes investigados, el 17% (94) tuvieron peticiones innecesarias de PTGO: 53 (53,4%) con glucemia capilar ≥ 140 mg/dl y DM previo y/o PTGO usado como cribado; 41 (43,6%) con glucemia capilar < 140 mg/dl, pero con diagnóstico de DM. El glucómetro se mostró preciso, con alta correlación ($r^2 = 0,97$, $p < 0,0001$) con la glucemia sérica. Los enfoques durante el cribado y la glucemia capilar evitaron la exposición innecesaria a la sobrecarga de glucosa en el 67% (63) de los pacientes.* ***Conclusión:*** *El alta prevalencia de peticiones innecesarias de PTGO destaca la necesidad de criterios para la solicitud de la PTGO, así como la estandarización de procedimientos para cribado en la consecución de esa prueba.*

Palabras clave: *prueba de tolerancia a la glucosa; diabetes* mellitus*; examens innecesarios; costos y análisis de costo.*

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder of multiple etiology that causes a picture of persistent hyperglycemia due to failure in insulin action and/or secretion[1, 2]. Diabetes mellitus type 2 (DM2) is the most prevalent type of the disease; it accounts for 90%-95% of all cases. Deficiency in incretins (gastrointestinal hormones secreted in response to nutrient ingestion, responsible for the increased insulin release and for the decreased glucagon release), in hepatic glucose regulation and production, besides increased lipolysis, defects in insulin action and/or secretion[2] are its main characteristics.

Besides being among the most prevalent chronic diseases, DM is associated with high morbidity in the whole world[3]. The global prevalence of people with diabetes in 2015 was 8.8%, around 415 million individuals. It is estimated that in 2040 this total will exceed 640 million. In 2015 Brazil was the fourth country with the highest prevalence of people with diabetes (approximately 14.3 million), second only to China, India, and the United States[4].

The treatment of DM exerts a relevant economic impact upon public health policies. Expenditures on diabetes are believed to be twice or three times heavier than those on subjects without diabetes, as this implies more intense use of health services, loss of productivity and prolonged care in the treatment of chronic complications[2, 4].

DM can be diagnosed by means of laboratory tests, such as fasting blood glucose ≥ 126 mg/dl, oral glucose tolerance test (OGTT) ≥ 200 mg/dl two hours after a 75 g oral glucose load or glycated hemoglobin (HbA1c) ≥ 6.5%. The diagnosis of gestational DM (GDM) by means of OGTT is indicated to pregnant women who have no previous DM diagnosis and between the 24 and 28 weeks of gestation[1, 2].

The OGTT is a test that measures an individual's ability to maintain blood glucose homeostasis after a glucose load; blood glucose can be the only detectable alteration in the beginning of DM due to the loss of first-phase insulin secretion capacity[2]. The test is useful in the investigation of GDM, in the inconclusive diagnosis of DM2, and for research of post-prandial reactive hypoglycemia[2, 5]. It presents high sensitivity for diagnostic screening of DM, but it must be indicated, preferably, for diagnosis of DM in pre-diabetic patients and/or those with associated risk factors, as family history of DM, obesity, GDM history or polycystic ovaries[5, 6].

OGTT requests that do not meet the criteria of its finality can be detected at the moment of test conduction, by means of procedures that consider the suitability and the necessity of challenging a patient to a glucose load. The inclusion of capillary blood glucose before the glucose load and screening to verify a previous DM history are important parameters to avoid unnecessary hyperglycemic pictures, preserving patients' health.

Acute hyperglycemia induced by the glucose load, as occurs in OGTT, produces reactive oxygen species and affects cellular redox state, damaging the function of pancreatic beta-cells. This results in dysfunction of their secretory activity, and can play and important role in progression to DM2[7].

The laboratory test standardization by means of protocols or guidelines that enhance the rational use of resources aimed at diagnosis and that inhibit the conduction of avoidable tests is very important, as there is a growing undervaluing of the clinical history of patients, what many times creates an unnecessary demand for complementary laboratory tests[8].

For the above reasons, and considering the possibility of requests without indication and the occurrence of undue loads glucose to patients, the present study was aimed at evaluating the prevalence of OGTTs conducted unnecessarily and the involved costs. It was also aimed at analyzing the efficiency of the adopted parameters to challenge the patient to a glucose load and the performance of the glucometer in the conduction of capillary blood glucose as a screening test.

METHOD

Cross-sectional study, with a descriptive and analytical approach conducted with 554 patients seen at Laboratório Central Municipal (LACEM) of Vitória da Conquista, Bahia, Brazil, who had OGTTs requested from January 1st to April 31st, 2018.

The research was carried out in the reference laboratory of the Unified Health System (SUS) for demands of tests in the region. That laboratory offers more than 130 types of tests, serves around 600 people per day, and runs over 90 thousand tests per month[9].

The population sample encompassed all the patients with OGTT requests, regardless of age, pre-existing diseases, or suitability for the test.

For data collection, we selected records of patients admitted at LACEM who underwent OGTT in the studied period (by means of laboratory records and by access to the Complab Advanced system version 6.9.6) for historical survey of patients' laboratory tests, with correlation with glycemic control.

The collected data were tabulated in the Microsoft® Office Excel and analyzed in the statistical package Epi Info™, version 7.2.1.0.

LACEM follows recommendations of Brazilian Society of Clinical Pathology/Laboratory Medicine [Sociedade Brasileira de Patologia Clínica/Medicina Laboratorial (SBPC/ML)] and the guidelines on DM diagnosis, which advocate that the conduction of OGTT requires fasting for at least eight hours. The test consists of collecting a fasting venous blood specimen; over five minutes, the patient must drink 75 g of glucose dissolved in 300 ml of water. Then, the patient must rest, with no ingestion of any food during the test, and two hours after the dose load, undergo a new of venous blood collection for measurement of serum glucose[1,2,5].

Despite the inexistence of recommendations or official position statements from societies calling for regulations of clinical laboratories for the conduction of capillary blood glucose before glucose challenge, the laboratory established parameters to detect unnecessary requests of OGTT, considering unfit those patients with reports of previous DM diagnosis using antidiabetic drugs and/or who had capillary blood glucose ≥ 140 mg/dl.

The capillary blood glucose conducted before the glucose challenge was measured by the glucometer Accu-Chek® Active (Roche), which has a detection range of 10 mg/dl-600 mg/dl and meets the ISO 15197 requirements[10]. Food and Drug Administration (FDA) recommends measuring ranges of glucometer to be between 10 mg/dl and 500 mg/dl. Ninety-five percent of the results of blood glucose > 75 mg/dl must have variation of up to ± 12%, and 98% of the results cannot exceed a variation of ± 15%, in comparison with the reference method[11].

The accuracy of the glucometer for capillary blood glucose previous to OGTT was assessed comparing capillary blood glucose with patients' serum glucose levels, by means of correlation analysis for samples paired by Student's *t* test, using software IBM SPSS® version 21™; $p < 0.05$ was considered.

The prevalence of unnecessary OGTT requests was estimated taking into consideration the undue OGTT request when prescribed to patients with history of DM or ordered as a screening test along with fasting glucose and/or HbA1c.

Based on the prevalence of unnecessary OGTT requests, an estimate of avoidable costs was made. A unified table of fund transfer from SUS was used (competence 11/2018 of the System of Management of the Table of Procedures, Medications, Orthoses, Prostheses, and Osteosynthesis Materials from SUS) for the cost of OGTT performed in two measurements[12].

This study was approved by the Ethics Research Committee of Instituto Multidisciplinar em Saúde of Universidade Federal da Bahia – report no. 2.692.916 from 5/6/2018.

RESULTS

Unnecessary OGTT requests

Data from 554 patients were collected: 449 women (218 pregnant) and 105 men, aged between 5 and 93 years, with mean age of 43 years. The prevalence of unnecessary OGTT requests, according to the established criteria, was estimated in 17%, what accounts for 94 patients. Out of this total, 53 (53.4%) presented capillary blood glucose ≥ 140 mg/dl, had previous DM and/or

OGTT as initial screening test. We must highlight that 41 (43.6%) of the unnecessary requests referred to patients with capillary blood glucose lower than 140 mg/dl, but had diagnostic criteria of DM, identified by the history of laboratory tests.

Out of the 94 unnecessary requests identified in the study, the standardization established by the laboratory avoided undue exposure of 67% (63) of the patients to glucose load. Among them, 10 (10.6%) reported diagnosed DM (blood glucose lower than 140 mg/dl) and 53 (53.4%) presented blood glucose higher than 140 mg/dl, with 40 (42.6%) known to have diabetes, and 13 (13.8%) with mild DM, serum glucose levels ≥ 126 mg/dl and/or HbA1c > 6.5%.

Some glucose loads could not be avoided, because 31 (36%) subjects denied having DM at the moment of the test and presented capillary blood glucose lower than 140 mg/dl. However, the history of previous tests revealed a diagnosis of DM.

Among the unnecessary OGTT requests for pregnant women, seven inadequate prescriptions were observed. Those women, according to previous tests, had already a diagnosis of DM: six of them did not undergo the test for presenting capillary blood glucose higher than 140 mg/dl, but one was subjected to the challenge, because she presented capillary blood glucose below the cut-off limit and did not report the previous diagnosis of the disease.

Efficiency of the cut-off parameter of capillary blood glucose and effectiveness of the glucometer for OGTT conduction

• The glucometer used in this study for capillary blood glucose as a screening method for OGTT presented excellent analytical sensitivity, linearity, and elevated correlation with serum glucose levels obtained in the laboratory.

• The analysis of mean glucose levels obtained with the glucose meter demonstrated little variation between the results in comparison with the mean serum glucose levels and standard error (1.64 mg/dl and 1.68 mg/dl) of the means (**Table**). The lowest values for capillary and venous glucose levels were 52 mg/dl in both methods, and the highest, 389 mg/dl and 395 mg/dl, respectively, demonstrating adequacy of the glucose meter concerning analytical sensitivity and linearity. The 60th, 70th, 80th, and 90th percentiles also presented good correlation (Table).

The result of matched blood glucose revealed that capillary blood glucose levels presented a mean difference of 9.1 mg/dl in relation to serum glucose levels. The paired analysis did not identify a significant difference, revealing a mean variation of 2.7% between the results. Student's *t* test for matched samples demonstrated strong correlation between both evaluated methods ($r^2 = 0.97$; $t = 23.58$; $p < 0.0001$).

The **Figure** presents the graph obtained by analysis of linear regression and demonstrates an elevated correlation between capillary (Accu-Chek® Active) and venous blood results.

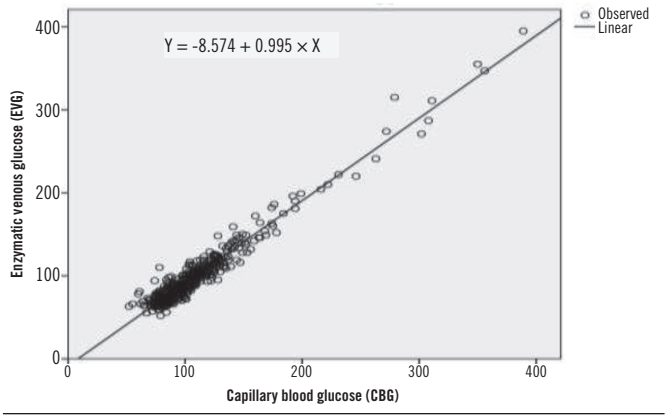

FIGURE – *Analysis of linear regression*

Costs generated by unnecessary requests

Nowadays, each OGTT performed for SUS costs R$ 3.63. Per year, cost estimates would be around R$ 6 thousand in the studied service. The expenses arising from unnecessary OGTT requests (R$ 969.21 annually) could be invested in other laboratory demands, besides avoiding unnecessary glucose loads to 267 patients.

TABLE – Analysis of correlation between matched samples of capillary and serum glucose

	Data of matched samples					Percentiles				Student's *t* test			CI: 95%
	Mean (mg/dl)	SD (mg/dl)	SEM (mg/dl)	Lowest (mg/dl)	Highest (mg/dl)	60th (mg/dl)	70th (mg/dl)	80th (mg/dl)	90th (mg/dl)	r^2	*p* value	*t*	df
CBG	106.46	37.82	1.64	52	389	105	111	121	138	-	-	-	-
EVG	97.37	38.67	1.68	52	395	95	102	110	128	-	-	-	-
CBG & EVG	9.08	8.86	0.39	-	-	-	-	-	-	0.97	0.0001	23.58	528

CBG: capillary blood glucose, measured by glucometer; EVG: venous glucose determined by enzymatic methods; SD: standard deviation; SEM: standard error of the mean; Lowest: lowest glucose concentration; Highest: highest glucose concentration; r²: correlation; df: degree of freedom; CI: confidence interval.

DISCUSSION

This study identified that in 17% of the requests, OGTT was targeted to patients with previous DM diagnosis and/or used as a first-choice tool to diagnose diabetes, what revealed the inappropriate use of the test. In addition, the literature does not support OGTT as a method for following up patients known to have the disease[1, 2, 5].

Although the criteria for OGTT request in pregnant women are well-established by guidelines – it must be carried out in women who do not have previous DM and between 24 and 28 weeks of gestation[1, 2] –, around 7.4% of undue requests of this test in the present study were directed to pregnant women with previous diagnosis of DM, bringing about unnecessary exposure and glucose load. The undervaluing of the previous clinical history and the non-observance of criteria related to follow-up and diagnosis of DM seem to have contributed to the prevalence of those requests. Anamnesis and clinical examination should be the main tools for diagnosis in clinical investigation, and complementary tests must be ordered only when necessary, as guiding elements to confirm diagnosis[13]. However, there is an overestimation of laboratory tests to the detriment of physical examination or clinical history, generating unnecessary requests and costs to the health system[9, 13, 14].

The use of adequate diagnostic methods avoids that patients undergo inadequate procedures. The guidelines of the American Diabetes Association (ADA) inform that the tests for diagnostic screening of DM are equally appropriate, yet the correlation among their results will not always happen[1]. On the other hand, Sociedade Brasileira de Diabetes (SBD) highlights glycated hemoglobin (HbA1c) as a first-choice method for diagnosis of DM, considering that its result is independent from patients' fasting status, besides suffering less disturbances in periods of stress or disease and having greater pre-analytical stability, although it also has some usage limitations[2, 15].

On an official position statement about the therapeutic conduct of DM2, SBD and SBPC/ML clarified that OGTT requests must be directed to pre-diabetic subjects, with fasting glucose of 100-125 mg/dl[5, 6].

Unnecessary OGTT requests generated an avoidable annual cost estimated in R$ 969.21. That value corresponds to the possible conduction of 523 glucose determinations and/or 123 HbA1c tests that would be useful for diagnosis and glycemic follow-up of many other patients[16, 17]. The unnecessary expenses with laboratory complementary tests have been the target of several studies, attributing undue requests to the lack of integration at the different levels of attention to health, or even to the lack of clinical correlation and prognosis due to the ineffective conduction of anamnesis and physical examination, what brings potentially avoidable costs[8, 18, 19].

Some studies stress the importance of implementing protocols or guidelines that aim at the enhancement of assistance and optimization of healthcare costs, promoting equity in prioritizing patients that will undergo complementary tests with the objective of improving management of the health system[8, 20]. The implementation of a guide to help prescriptions of laboratory tests at a hospital resulted in a meaningful reduction of unnecessary requests, which ranged from 38% to 71.5%, depending on the type of test ordered[21].

Today there is no legislation or official position statement as to the necessity of capillary blood glucose before a glucose load and which level of glucose is acceptable for the conduction of OGTT in a safe form. SBPC/ML criticizes the attitude of some laboratories that just suspend the conduction of OGTT when capillary blood glucose is ≥ 180 mg/dl, foreseeing that the request and the conduction of the OGTT is undue, since in this level of glucose the diagnosis of DM is presumed[5]. Our study demonstrated that the tolerated limit of capillary blood glucose (≥ 140 mg/dl) was effective, because all the patients who were detected by that parameter fit into unnecessary requests.

The approaches with interviews during screening along with the capillary glucose result before the glucose load were useful for decision taking regarding patients' suitability to proceed with the test. We must emphasize the necessity to verify the glucometer accuracy. The detection capacity of the monitor used in the study was compatible with the FDA recommendations and showed variation of 2.7% in comparison with the enzymatic method for glucose measurement. Observing blood glucose levels higher than 100 mg/dl (the interest of our study), the variation did not exceed 12 mg/dl, being in accordance with the tolerated by FDA[11]. An analogous study with the glucose meter Accu-Chek Compact (Roche) also did not find a statistically significant difference between capillary and venous glucose blood levels, neither high correlation between results[22], what confirms the data from our study. Thus, the use of the glucometer in the screening of OGTT proved adequate for its aim. It is important to highlight that the use of this instrument in the laboratory must go through previous validation according to current rules[23, 24].

Evidence points that patients' clinical characteristics, type and form of handling the instrument used to measure glucose can interfere in the accuracy and reliability of results[25]. Therefore, it is recommended that the professional is qualified for correctly handling the glucose meter.

CONCLUSION

This study demonstrated that there is a significant prevalence of unnecessary OGTT requests, including for groups with well-established request criteria, what is the case of pregnant women. The undervaluing of the previous clinical history and the non-observance of criteria for follow-up and diagnosis of DM seem to have contributed to the great prevalence of those requests.

Laboratory tests are the most frequently used diagnostic interventions to support clinical decisions. However, it is necessary that prescribers and laboratory professionals promote their rational use. Professional updating by a guide of criteria for OGTT requests is a viable strategy to be adopted for prescribers' instruction.

The glucometer used in this study presented analytical sensitivity, linearity, and high correlation with the reference method, being compatible with the standards established by the FDA. Moreover, it proved adequate to foresee unnecessary OGTTs, since it is validated and monitored. The cut-off limit of capillary blood glucose ≥ 140 mg/dl established to assess patients' suitability before glucose load proved efficient, as all the patients detected by this parameter fit in unnecessary requests. The avoidable costs generated by the unnecessary requests can be directed to other tests to the follow-up of patients with DM, aimed at detecting chronic complications that significantly increase the healthcare costs of patients with diabetes.

Furthermore, it is worth noting that entities ruling laboratories need to recommend the adoption of pre-OGTT screening practices, to avoid glucose loads to patients known to be diabetic and prevent the conduction of unnecessary tests.

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