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An Evidence-Based Laboratory Medicine (EBLM) Test to Help Doctors in the Assessment of the Pancreatic Endocrine Function

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Abstract : Pancreatic endocrine diseases include pathologies like insulin resistance (IR), prediabetes, and type 2 diabetes mellitus (DM2). Some of them are highly prevalent in the U.S.—40% of U.S. adults have IR, 38% of U.S. adults have prediabetes, and 12% of U.S. adults have DM2—, as reported by the National Center for Biotechnology Information (NCBI). Building upon this imperative, the objective of the present study was to develop a non-invasive test for the assessment of the patient's pancreatic endocrine function and to evaluate its accuracy in detecting various pancreatic endocrine diseases, such as IR, prediabetes, and DM2. This approach to a routine blood and urine test is based around serum and urine biomarkers. It is made by the combination of several independent public algorithms, such as the Adult Treatment Panel III (ATP-III), triglycerides and glucose (TyG) index, homeostasis model assessment-insulin resistance (HOMA-IR), HOMA-2, and the quantitative insulin-sensitivity check index (QUICKI). Additionally, it incorporates essential measurements such as the creatinine clearance, estimated glomerular filtration rate (eGFR), urine albumin-to-creatinine ratio (ACR), and urinalysis, which are helpful to achieve a full image of the patient's pancreatic endocrine disease. To evaluate the estimated accuracy of this test, an iterative process was performed by a machine learning (ML) algorithm, with a training set of 9,391 patients. The sensitivity achieved was 97.98% and the specificity was 99.13%. Consequently, the area under the receiver operating characteristic (AUROC) curve, the positive predictive value (PPV), and the negative predictive value (NPV) were 92.48%, 99.12%, and 98.00%, respectively. The algorithm was validated with a randomized controlled trial (RCT) with a target sample size (n) of 314 patients. However, 50 patients were initially excluded from the study, because they had ongoing clinically diagnosed pathologies, symptoms or signs, so the n dropped to 264 patients. Then, 110 patients were excluded because they didn't show up at the clinical facility for any of the follow-up visits—this is a critical point to improve for the upcoming RCT, since the cost of each patient is very high and for this RCT almost a third of the patients already tested were lost—, so the new n consisted of 154 patients. After that, 2 patients were excluded, because some of their laboratory parameters and/or clinical information were wrong or incorrect. Thus, a final n of 152 patients was achieved. In this validation set, the results obtained were: 100.00% sensitivity, 100.00% specificity, 100.00% AUROC, 100.00% PPV, and 100.00% NPV. These results suggest that this approach to a routine blood and urine test holds promise in providing timely and accurate diagnoses of pancreatic endocrine diseases, particularly among individuals aged 40 and above. Given the current epidemiological state of these type of diseases, these findings underscore the significance of early detection. Furthermore, they advocate for further exploration, prompting the intention to conduct a clinical trial involving 26,000 participants (from March 2025 to December 2026).

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