Differentiating Pancreatic Ductal Adenocarcinoma (PDAC) from individuals with symptoms suggestive of type II diabetes, with ROC AUC values above 0.95

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Introduction

Discriminating PDAC from non-PDAC symptomatic individuals represents a more challenging task than distinguishing PDAC from healthy controls.

Currently available tests have been shown to be inadequate in delivering clinically actionable results, e.g. CA19-9 cannot alone discriminate between PDAC and other disease conditions in the gastrointestinal tract.

Objective

This study aimed to evaluate if IMMray™ PanCan-d could, with high accuracy, separate patients with PDAC (stage I-IV) from individuals with various non-specific but concerning symptoms not caused by PDAC, which mirrors the clinical setting for gastroenterologists.

Patients and Methods

Patient samples from 136 PDAC (stage I-IV), 570 non-PDAC symptomatic individuals and 217 healthy individuals were tested using IMMray™ PanCan-d as well as a CA19-9 ELISA assay.

To minimize confounding and pre-analytical variables, all patient samples were collected and processed using the same standard operating procedures, stored at -80°C and tested within a year after collection. Data analysis was performed using Immunovia software algorithms and SVM ROC AUC values were determined for the different groups.

Results

A. Symptomatic vs. PDAC

B. Healthy vs. PDAC

C. Diabetes vs. PDAC

D. Controls vs. PDAC Stages I & II

Fig 1. In total, 937 individuals were analyzed. Combining IMMray™ PanCan-d with CA19-9, the results showed SVM ROC AUC values of 0.97, 0.98 and 0.96 differentiating PDAC vs. non-PDAC symptomatic individuals, healthy controls and type II diabetes, respectively. Similar results were achieved for all stages of PDAC.

Conclusions

The current study showed for the first time that IMMray™ PanCan-d has the capacity to differentiate between symptomatic, non-PDAC individuals, including type II diabetes, and all different stages of PDAC. These findings have significant clinical implications for individuals attending primary and secondary care units with non-specific but concerning symptoms where PDAC may be suspected.

Next steps

Prospective validation studies are underway with 10,000 subjects in the three high risk groups for pancreatic cancer: PanFAM-I (predisposed familial), PanSYM-I (any symptoms) and PanDIA-I (new onset type II diabetes after 50 years of age).

References


2. PanFAM-I vs. PanSYM-I vs. PanDIA-I, See below.

2. PanFAM-1 detail on ClinicalTrials.gov, Identifier: NCT03693378.