



EXOCRINE PANCREATIC FUNCTION TESTS - 13C-BREATH TEST AND FECAL ELASTASE

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SUMMARY

Introduction. In this study we report our 6 years experiences with non-invasive test of exocrine pancreatic function - breath test with ¹³C-mixed triglycerides (¹³C-MTG) and fecal elastase-1 (FELA).

Aims & Methods. The study group was 225 subjects with suspected chronic pancreatitis (CHP). The diagnosis of CHP was confirmed in 151 patients, categorised to four groups (A, B, C, D) by two aspects - morphology and function, 71 cases without CHP were used as control group. ¹³C-MTG test was performed with 250mg Glycerol-1,3-dioctadecanoate-2-octanoate-1-¹³C. ¹³C/¹²C ratio were analysed by infrared NDIRS analysers (Isodiagnostika-Canada, HellFAN-Germany). Fecal elastase 1 (FELA) were determined using ELISA with monoclonal antibody (ScheBoTech, Germany).

Results. Fecal elastase as well as ¹³C-MTG cumulative recovery (cPDR) significantly distinguishes severe CHP (grade D) from all other groups, mild CHP (grade A) is significantly higher compared to other groups of CHP. Concordant results of ¹³C-MTG and FELA were found in 79.7%. The highest percentage (40.1%) of discordant results (low FELA, normal ¹³C-MTG) were in groups CHP-B and CHP-D, in patients with morphological complications, resulting in low FELA, but still clinically normal functions and normal ¹³C-MTG.

Conclusions. Measurement of fecal elastase 1 is simple, non-invasive, robust test, which well correlates with morphological, static, extent of tissue damage. ¹³C-MTG breath test is better in evaluation of dynamic and kinetic aspects, real digestive ability and response to stimulation. ¹³C-MTG breath test is, contrary to FELA, suitable to evaluate pancreatic supplementation therapy. Two different aspects of exocrine pancreatic function could be evaluated by two laboratory methods - fecal elastase and ¹³C-breath test.

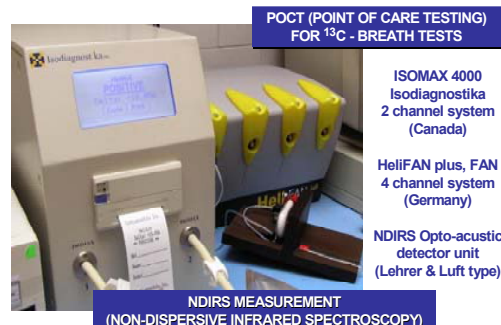
CHP PATIENTS GROUPS

225 patients susp. for chronic pancreatitis,
151 CHP confirmed by imaging methods
ERCP - CT - US
71 subjects - CHP excluded

FUNCTIONS	MORPHOLOGY	
	NO	YES
clinical manifested function insufficiency steatorrhea diabetes mellitus	NO	YES
	CHP - A n = 50	CHP - B n = 31
YES	CHP - C n = 29	CHP - D n = 41

CHP group	NON	A	B	C	D
number	71	50	31	29	41
age (mean)	45.4	49.8	48.1	56.1	51.1
male : female	0.87	1.00	2.10	1.42	7.20

NDIRS ANALYSERS



FECAL ELASTASE

STOOL SAMPLES - SUBJECTS

FECAL SAMPLES WERE FROZEN AND STORED AT -70 °C
368 SAMPLES WERE ROUTINELY ANALYSED FOR ELASTASE-1 BY MONOCLONAL ELISA, 213 PATIENTS WERE CLASSIFIED BY A-B-C-D GROUPS, 183 SUBJECTS WITH SUSP. CHP WERE TESTED WITH ¹³C-MTG AS WELL.

MONOCLONAL ELASTASE-1 ELISA

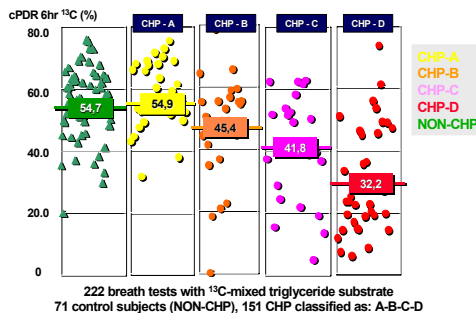
SCHEBO ELISA ROUTINELY USED SINCE 1999
MONOCLONAL ANTIBODY TO ELASTASE IIA ISOTYPE
NORMAL RESULTS > 200 µg/g, SEVERE INSUFFICIENCY < 100 µg/g

POLYCLONAL ELASTASE ELISA

BIOSEV ELISA COMPARED TO SCHEBO TEST IN 277 SUBJECTS
POLYCLONAL ANTIBODY TO ELASTASE IIIA AND IIIB ISOTYPES
NORMAL RESULTS > 200 µg/g, SEVERE INSUFFICIENCY < 100 µg/g

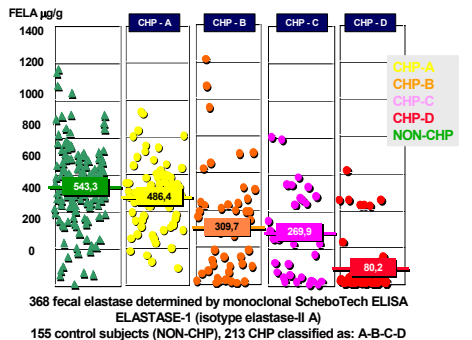
¹³C-MTG BREATH TEST

DYNAMIC ASPECT

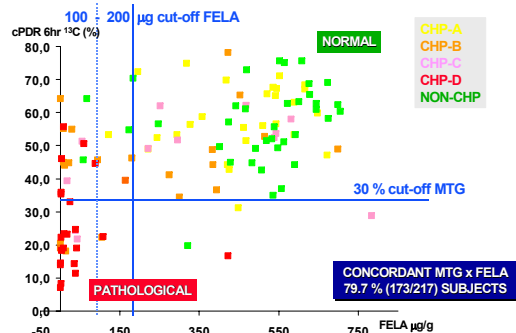


FECAL ELASTASE

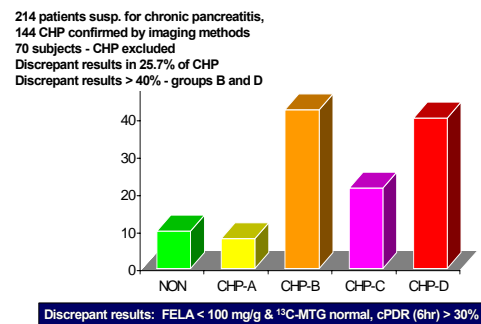
STATIC ASPECT



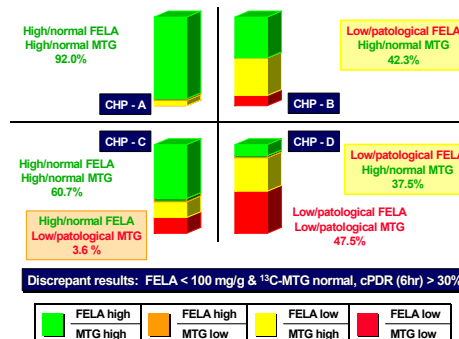
STATIC & DYNAMIC ASPECTS



STATIC & DYNAMIC ASPECTS



STATIC & DYNAMIC ASPECTS



¹³C-MTG BREATH TEST

TEST PROCEDURE

TWO SAMPLE BAGS AFTER OVERNIGHT FASTING
PANCREATIC SUBSTITUTION THERAPY 3DAY EXCLUDED
STIMULATION MEAL
4 CRISP SLICES, MAIZE WITH FIBRES
(WITHOUT CHOLESTEROL, GLUTEN-FREE)
2 x 10g RAMA (VEGETABLE FAT WITHOUT MILK PROTEINS)
TEST SUBSTANCE ADMINISTRATION - 250mg ¹³C-MTG
STIRRED INTO VEGETABLE FAT
HOURLY BREATH-BAG SAMPLING (1 - 6 hr)

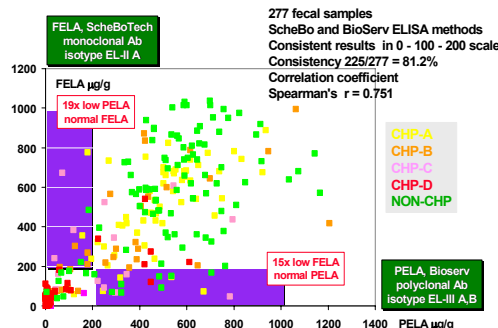
TEST ANALYTICS

DOB MEASUREMENT OF EACH SAMPLE ¹³CO₂ : ¹²CO₂ (in %_o)
T_x SAMPLE AGAINST T₀ (DOB = Delta Over Baseline)

EVALUATION OF PANCREATIC INSUFFICIENCY

BSA CALCULATED (BASED ON WEIGHT, HEIGHT)
BMR AND CO₂ PRODUCTION CALCULATED (MS Excel)
CUMULATIVE RECOVERY FOR 6 HOURS CALCULATED

FECAL ELASTASE - II or III



CONCLUSIONS

¹³C-mixed triglyceride test (MTG) for exocrine pancreatic function was performed in 225 patients suspected of chronic pancreatitis using 250mg of Glycerol-1,3-dioctadecanoate-2-octanoate-1-¹³C. Cumulative recovery < 30% was interpreted as pancreatic insufficiency. When compared with fecal elastase level we found 79.7% consistent results, in 217 subjects.

Five different human pancreatic elastases (PA I, IIA, IIB, IIIA, IIIB) are known, of which human pancreatic Elastase I is not expressed in the adult pancreas. All antibodies that are commonly used in a polyclonal ELISA BioServ preferentially detect human Elastase Isoforms IIIA and IIIB. Clinical literature that describes human elastase-1 activity in the pancreas is actually referring to elastase IIA (ELISA ScheBo).

277 fecal samples were analysed using both methods ScheBo and BioServ ELISA. Consistent results in 0 - 100 - 200 scale were found in 225/277 = 81.2%.

Discrepant results: FELA < 100 mg/g & ¹³C-MTG normal, cPDR (6hr) > 30% we found mainly in groups CHP-B and CHP-D, 42.3% and 40.0% of CHP confirmed patients.

Measurement of fecal elastase is simple, non-invasive, robust test, which well correlates with morphological, static, extent of tissue damage. ¹³C - MTG-BT is better in evaluation of dynamic and kinetic aspects. Performance of both tests could improve clinical values.

This poster could be on-line downloaded as PDF file (Adobe Acrobat) on my web-page:
http://www1.11.un.cz/~kocna/uegw_2008_mtg.pdf