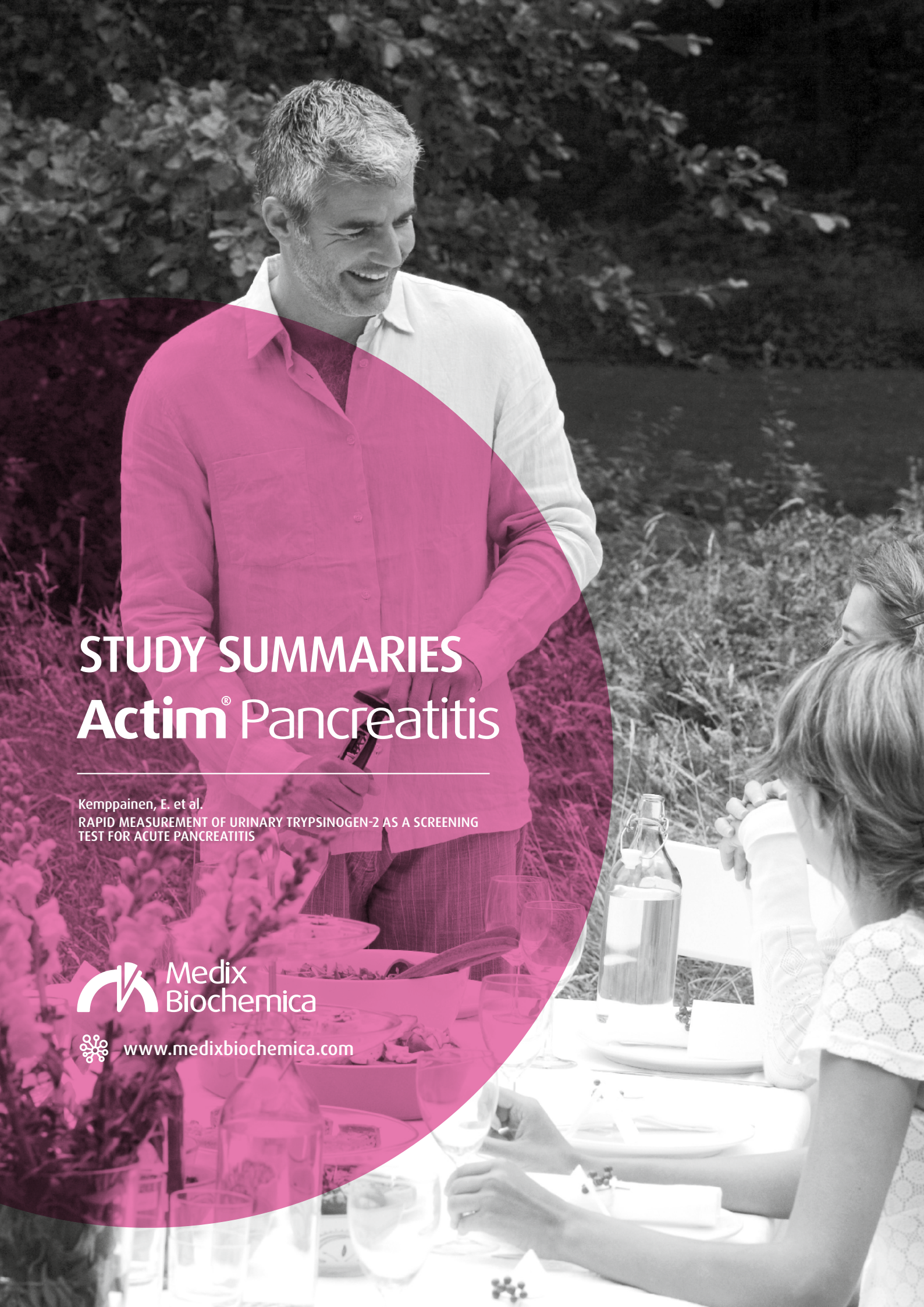

STUDY SUMMARIES
Actim® Pancreatitis

Kemppainen, E. et al.
RAPID MEASUREMENT OF URINARY TRYPSINOGEN-2 AS A SCREENING TEST FOR ACUTE PANCREATITIS

Medix Biochemica

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Kemppainen, E., Hedström, J., Puolakkainen, P., Saini, V., Haapiainen, R., Perhoniemi, V., Osman, S., Kivilaakso, E., and Stenman, U-H.

RAPID MEASUREMENT OF URINARY TRYPSINOGEN-2 AS A SCREENING TEST FOR ACUTE PANCREATITIS

The New England Journal of Medicine (1997) 336:1788-1793.

"In patients with acute abdominal pain seen in the emergency department, a negative dipstick test for urinary trypsinogen-2 rules out acute pancreatitits with a high degree of probability."

Immediate diagnosis of severe acute pancreatitis is important since early intensive therapy is likely to be beneficial. However, the diagnosis of acute pancreatitis is often problematic. Measurement of amylase and lipase is the principal laboratory method for diagnosing acute pancreatitis, but the sensitivity and specificity of the assays for these enzymes are considered unsatisfactory. Instead, measurement of trypsinogen is considered useful in diagnosing acute pancreatitis and assessing its severity. We have developed a rapid dipstick test for the detection of elevated trypsinogen-2 concentrations in urine.

Method

The study group consisted of 500 consecutive patients (306 men, 194 women) with acute abdominal pain seen in the emergency department at Helsinki University Central Hospital or Helsinki City Hospital between October and December 1995. The mean duration of pain was 1.1 days (from 0.1 to 4 days). The mean age was 45 years (from 17 to 90 years).

Urine samples were obtained from all patients. Samples were tested immediately with the strips for trypsinogen-2 and amylyase. Trypsinogen-2 and amylase concentrations in urine were also determined in all patients by quantitative methods. Dipstick test for urinary trypsinogen-2 is an immunochoromatographic test produced by Medix Biochemica, Finland. At trypsinogen-2 concentrations higher than 50 ng/ml, a blue line develops. Test was considered positive if a clear blue line was detected.

After clinical evaluation also the serum amylase concentrations were determined. The criteria for a diagnosis of acute pancreatitis were characteristic clinical findings and very high amylase concentrations (serum > 900 U/l, and urinary > 6000 U/l) (19 patients), clinical findings combined with an elevated amylase concentration (> 300 U/l in serum or > 2000 U/l in urine) and CT or ultrasonographic findings typical of acute pancreatitis (28 patients), or a characteristic clinical presentation and positive findings on contrast-enhanced CT in patients without elevated amylase concentrations at presentation (6 patients).

Results

Acute pancreatitis was diagnosed in 53 patients (12 women, 41 men) with a mean age of 42 years (24-65). The result of the urinary trypsinogen-2 dipstick [Actim Pancreatitis] test were positive in 50 patients. The results were also positive in 21 of the 447 patients with abdominal pain but no evidence of acute pancreatitits. The sensitivity, specificity, positive and negative predictive values of the [Actim Pancreatitis] test are shown in Table 1

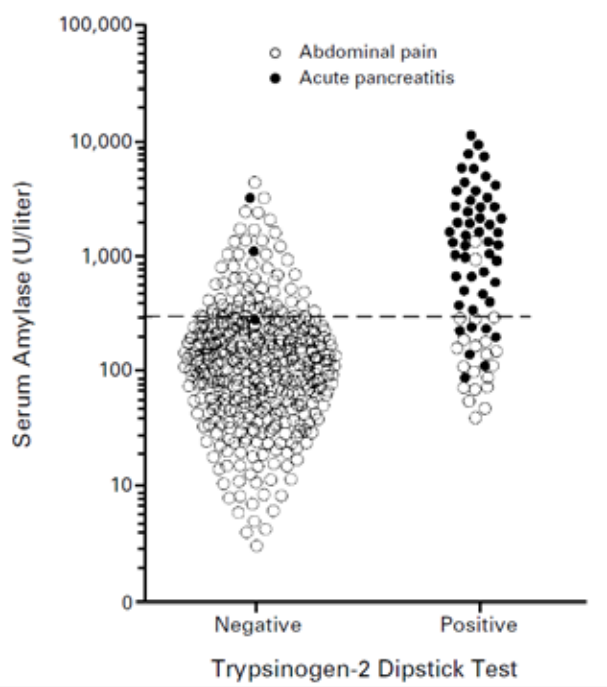
TABLE 1. Clinical performance of the tests

	Specificity	Sensitivity	PPV	NPV
Trypsinogen-2 dipstick [Actim Pancreatitis]	95%	94%	68%	99%
Quantitative trypsinogen-2	92%	93%		
Amylase dipstick	79%	89%		

The correlation between the results of the urinary trypsinogen-2 dipstick and those of the serum amylase assay is shown in Figure 1.

FIGURE 1.

Results of the urinary trypsinogen-2 dipstick test in relation to serum amylase concentrations in 53 patients with acute pancreatitis and 435 patients with abdominal pain from other causes. The upper reference limit for serum amylase (300 U per liter) is indicated by the dashed line.



Conclusion

The urinary trypsinogen-2 dipstick test detected acute pancreatitis more accurately than quantitative serum or urinary amylase determinations. Intrapancreatic activation of trypsin is believed to play an essential part in acute pancreatitis, especially in the necrotizing form of the disease. The most valuable clinical feature of the dipstick test was its ability to detect all cases of severe acute pancreatitis. In the study, it was found that the concentration of trypsinogen-2 remains elevated for 4 to 30 days in urine. A urinary screening test could help reduce the risk of misdiagnosing acute pancreatitis in patients seen in the emergency department. A negative test result with the urinary trypsinogen-2 dipstick test rules out acute pancreatitis with a high probability and a positive result identifies patients in need of further evaluation.

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