

The Predictive Value of Urinary Trypsinogen Dipstick versus Amylase and Lipase in Early Diagnosis of Acute Pancreatitis

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Abstract

Background: Acute pancreatitis is a common cause of acute abdomen presenting to the emergency. It can mimic most cases of acute abdomen clinically like cholecystitis, perforated duodenal ulcer etc. Acute pancreatitis accounts for 5% of patients presenting with abdominal pain to emergency. **This study aimed to** investigate the predictive role of Urinary Trypsinogen-2 (UT-2) dipstick test in early diagnosis of acute pancreatitis in comparison with serum amylase and lipase levels. **Methods:** This cross-sectional study was carried out on 104 patients who were suspected to have acute pancreatitis. Patients were categorized into two groups: Group I: Patients with acute pancreatitis (have elevated lipase and amylase level (above 300 IU/L in serum) and diagnostic findings on contrast-enhanced computed tomography (CECT). Group II: Patients with other abdominal disorders. Blood samples were analyzed for serum amylase, lipase, and UT-2 dipstick, while CECT confirmed diagnoses. **Results:** Of the patients, 12 (11.54%) were diagnosed with acute pancreatitis. UT-2 was significantly higher in group I than group II ($P < 0.001$). UT-2 can significantly predict acute pancreatitis (P value < 0.001) with 91.7% sensitivity, 96.7% specificity, 78.6% PPV, 98.9% NPV and 96.2% accuracy. So, UT-2 can significantly predict acute pancreatitis better than serum amylase and serum lipase. **Conclusion:** UT-2 dipstick was a good predictor even better than serum amylase and serum lipase for early diagnosis of acute pancreatitis.

Keywords: Urinary Trypsinogen Dipstick; Serum Amylase; Serum Lipase; Acute Pancreatitis.

Introduction:

Acute pancreatitis is a common cause of acute abdomen presenting to the emergency. It can mimic most cases of acute abdomen clinically like cholecystitis, perforated duodenal ulcer etc. Acute pancreatitis accounts for 5% of patients presenting with abdominal pain to surgical emergency (1).

Although most patients with pancreatitis have a mild disease that resolves spontaneously, 5-10 % are present with severe disease, which is characterized by a protracted clinical course, pancreatic necrosis, and Multiple organ dysfunction syndrome (MODS) and is associated with increased morbidity and mortality. Early diagnosis of pancreatitis is essential because therapy may improve outcome (2).

Acute pancreatitis clinical representation is very much like many other acute abdomen conditions, the diagnosis only based on symptoms and signs is difficult. An Atlanta classification has revised the standard form of performing diagnosis of acute pancreatitis. Here, for the purpose of examining the acute condition of pancreatitis, assistance is taken from 2 or more criteria. The first criteria are analyzing serum amylase or lipase above 300 IU/L (3, 4). A second criterion is for examining abdominal pain. The third criteria are characteristic findings in Computed tomography (CT) scan. None of the above is very effective in diagnosis of the disease in early stage. Contrast enhanced CT-scan, although it is

considered gold standard, it takes at least 72 to 96 hours to show characteristic finding for diagnosis (5,6).

Serum amylase levels increase within 2-12 hours and return to normal in 3-5 days and serum lipase rises within 48hours and remains elevated longer than serum amylase (8-14 days) (7). Measurement of amylase or lipase is the principal laboratory method for diagnosing acute pancreatitis, but the sensitivity and specificity of the assays for these enzymes are considered unsatisfactory. Both the serum markers have their own advantages and disadvantages based on different clinical setting as elaborated later (8).

Trypsinogen is a 25 kD pancreatic proteinase with the two main isoenzymes, trypsinogen-1 (cationic) and trypsinogen-2 (anionic). Urinary trypsinogen-2 (UT-2) is secreted in low concentration in normal individuals. In the initial phase of the acute pancreatitis disease, it is strongly raised (9).

However, for the purpose of examining the initial phase acute pancreatitis UT-2 dipstick test is taken into consideration. It is effective as well as a simple method of performing testing. Moreover, a dipstick test is used for the purpose of assessing the concentration in UT-2. This test is simple and can be taken through strip (10). So, we designed this trial for further investigation of the predictive value of UT-2 dipstick compared to the

standard amylase and lipase in early diagnosis of acute pancreatitis.

The purpose of this study is to investigate the predictive role of UT-2 dipstick tests in early diagnosis of acute pancreatitis in comparison with serum amylase and lipase levels.

Patients and methods:

This study was conducted at Benha University Hospital

Patients:

This cross-sectional study was carried out on 104 patients who were suspected to have acute pancreatitis during the period from October 2023 to October 2024.

Inclusion criteria were patients aged more than 18 years of both sexes, susceptible to acute pancreatitis [patients suffering from consistent clinical findings (epigastric pain, nausea, and vomiting)].

The exclusion criteria were patients with stage 3 or 4 renal disease and/or oliguria (urine output less than 0.5 ml/kg/h for 24 h), associated with chronic calcific pancreatitis, pancreatic cancer as well as critical condition of pancreatitis, and pregnancy.

An informed written consent was obtained from the patients. Every patient received an explanation of the purpose of the study and had a secret code number. The study was done after being approved by the Research Ethics Committee, Faculty of Medicine, Benha University.

Grouping:

Patients were categorized into two groups: **Group I:** Patients with acute pancreatitis (have elevated amylase level (above 300 IU/L in serum) and diagnostic findings on CECT. **Group II:** Patients with other abdominal disorders.

Methods:

All susceptible patients were subjected to the following:

Thorough history taking, including personal details (age, sex), medical history (gallbladder stones, diabetes mellitus, cardiovascular, chest, hepatic diseases, dyslipidemia, chronic kidney disease), history of surgeries, and drug habits. Patients presented with abdominal pain, with details on onset, cause, location, and radiation, along with symptoms like vomiting and bowel habit changes. A complete clinical examination was followed by routine lab tests (CBC, renal and liver function, coagulation profile) and specific tests (UT, serum lipase/amylase). Radiological assessments included ultrasonography and CECT.

Acute pancreatitis diagnosis required two of three criteria: typical abdominal pain, elevated serum lipase/amylase, or characteristic CECT findings (11). 11.5% of suspected cases were diagnosed with acute pancreatitis, while others were diagnosed with conditions like acute gastritis or liver abscess. UT-2 showed high sensitivity, specificity, and predictive value compared to serum amylase and lipase,

proving to be a simple, cost-effective early detection method.

Approval code : MS:29-11-2023

Sampling:

Blood sampling: A 5.0 ml fasting venous blood sample were drawn from each patient, with 2.0 ml placed in an EDTA tube for CBC, and the rest in a plain tube for LFT, RFT, serum amylase, and lipase estimation. Serum lipase was measured via the calorimetric method, where the lipase substrate is cleaved at an alkaline pH to form dialkyl-glycerol and an unstable compound, which degrades into glutaric acid and methyl-resorufin. The intensity of the red dye formed is proportional to lipase activity, measured at 578 nm (reference: < 60 U/L) (12). Serum amylase was measured via the coupled enzymatic assay method, where the substrate (CNP3) is hydrolyzed by α -amylase to produce 2-chloro-4-nitrophenol, with activity measured (reference: < 90 U/L) (13). Ultrasonography and CECT were performed on days 4-5.

Urine sampling: For the UT-2 dipstick test, random urine samples were collected from patients upon admission and tested immediately. After centrifugation, the supernatant was used for UT-2 detection using a rapid dipstick test based on the immunochromatography principle. The test strip was briefly dipped into the urine, allowing UT-2 to bind to monoclonal antibody-labeled blue latex particles. A clear blue line in the catching zone within 5 minutes indicated a positive result, while the

control line confirmed proper strip function. If the control line was absent, the test was repeated. The test's detection limit was 50 g/L. UT-2 concentration was further measured by a quantitative immune-enzymometric assay (IEMA), with samples stored at -20°C for later analysis.

Sample size:

Assuming the prevalence of acute pancreatitis was 11.6% (14) and the target population was 200, at 95% CI and effect size =1, the estimated sample was 104 Cases.

Statistical analysis

Statistical analysis was performed using SPSS v26 (IBM Inc., Chicago, IL, USA). The Shapiro-Wilks test and histograms were used to assess data normality. Parametric variables were presented as mean \pm standard deviation (SD) and compared between groups using the unpaired Student's T-test, while qualitative variables were presented as frequency (%) and analyzed using the Chi-square or Fisher's exact test. Diagnostic performance was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Receiver Operating Characteristic (ROC) curve analysis assessed overall test performance, with an area under the curve (AUC) >50% indicating acceptable performance, and AUC close to 100% representing the best performance. A two-tailed p-value < 0.05 was considered statistically significant.

Results:

This cross-sectional study was carried out on 104 patients (42 females and 62 males) aged more than 18 years who were suspected of having acute pancreatitis to investigate the predictive role of UT-2 dipstick test in early diagnosis of acute pancreatitis in comparison with serum amylase and lipase levels.

After the standard serum lipase and amylase test and CECT reports of all susceptible patients, patients will be categorized into two groups:

Group I: Patients with acute pancreatitis (have elevated amylase and lipase levels (above 300 IU/L in serum) and diagnostic findings on CECT.

Group II: Patients with other abdominal disorders, rather than acute pancreatitis.

A total of 12 patients (11.54%) were diagnosed with acute pancreatitis confirmed by CECT

Age and sex were insignificantly different between both groups. DM, hypertension, chronic kidney disease, hepatic diseases and dyslipidemia were insignificantly different between both groups. The history of gall bladder stone and previous operations were insignificantly different between both groups. (**Table 1**)

Hb, platelets and WBCs were insignificantly different between both groups. ALT, AST, ALP, total bilirubin and direct bilirubin were

significantly higher in group I than group II (P value<0.001).

Creatinine was significantly higher in group I than group II (P value<0.001). INR was insignificantly different between both groups. Serum amylase and serum lipase were significantly higher in group I than group II (P value<0.001). UT-2 was significantly higher in group I than group II (P<0.001) (table 2).

Serum amylase can predict acute pancreatitis (P value<0.001 and AUC=0.942) at cut off >597U/L with 83.3% Sensitivity, 78.3 %specificity, 33.3% PPV and 97.3% NPV. (**Figure 1-table3**)

Serum lipase can predict acute pancreatitis (P value <0.001 and AUC=0.944) at cut off >620 U/L with 91.6 %sensitivity, 76.1 %specificity, 33.3% PPV and 98.6% NPV. UT-2 can significantly predict acute pancreatitis (P value<0.001) with 91.7% sensitivity, 96.7% specificity, 78.6% PPV, 98.9% NPV and 96.2% accuracy. (**Figure 1-table3**)

A number of 12 patients diagnosed as acute pancreatitis depending on CECT . While +ve dipstick patients of about 14 patients (11 true positive patients confirmed by CECT and 3 false negative patients who did not have pancreatitis by CECT) (table 4).

Ninety-two patients confirmed not to have pancreatitis. Ninety patients of them have negative dipstick test (89 patients true negative and 1 patient false negative *confirmed by CECT) (table 4).

UT-2 can significantly predict acute pancreatitis (P value<0.001) with 91.7% sensitivity, 96.7% specificity, 78.6% PPV, 98.9% NPV and 96.2% accuracy. (Table 4)

So in comparison with serum amylase and serum lipase for prediction of acute pancreatitis. UT-2 can significantly predict acute pancreatitis better than serum amylase and serum lipase.

Table 1: Demographic data, comorbidities, and history of gall bladder stone and previous operations of the studied groups.

		Group I (n=12)	Group II (n=92)	P value
Age (years)	Mean ± SD	52.83 ± 15.34	50.49 ± 15.4	0.621
	Range	31 - 74	25 - 75	
Sex	Male	5 (41.67%)	57 (61.96%)	0.133
	Female	7 (58.33%)	35 (38.04%)	
DM	Yes	3 (25%)	24 (26.09%)	1
	No	9 (75%)	68 (73.91%)	
Hypertension	Yes	3 (25%)	30 (32.61%)	0.748
	No	9 (75%)	62 (67.39%)	
Chronic kidney disease	Yes	0 (0%)	3 (3.26%)	1
	No	12 (100%)	89 (96.74%)	
Hepatic diseases	Yes	1 (8.33%)	4 (4.35%)	0.465
	No	11 (91.67%)	88 (95.65%)	
Dyslipidemia	Yes	1 (8.33%)	15 (16.3%)	0.687
	No	11 (91.67%)	77 (83.7%)	
History of gall bladder stone	Yes	5 (41.67%)	25 (27.17%)	0.297
	No	7 (58.33%)	67 (72.83%)	
History of previous operations	Yes	2 (16.67%)	10 (10.87%)	0.627
	No	10 (83.33%)	82 (89.13%)	

Table 2: Creatinine, INR, serum amylase, serum lipase, and urinary trypsinogen II of the studied groups.

		Group I (n=12)	Group II (n=92)	P value
Creatinine (mg/dl)	Mean ± SD	1.4 ± 0.14	1.08 ± 0.2	<0.001*
	Range	1.2 - 1.6	0.8 - 1.4	
INR	Mean ± SD	0.93 ± 0.2	0.94 ± 0.18	0.754
	Range	0.6 - 1.2	0.7 - 1.2	
Serum amylase (U/L)	Mean ± SD	718.58 ± 95.57	286.77 ± 205.62	<0.001*
	Range	591 - 920	111 - 642	
Serum lipase (U/L)	Mean ± SD	738.25 ± 302.5	253.34 ± 240.53	<0.001*
	Range	140 - 1055	88 - 694	
Urinary trypsinogen II	Positive	11 (91.67%)	3 (3.26%)	<0.001*
	Negative	1 (8.33%)	89 (96.74%)	

Table 3. Role of s. amylase an s. lipase in prediction of acute pancreatitis

	Cut off	Sensitivity	Specificity	PPV	NPV	AUC	P value
Serum amylase (U/L)	>596	83.3%	78.3%	33.3%	97.3%	0.942	<0.001*
Serum lipase (U/L)	>620	91.6%	76.1%	33.3%	98.6%	0.944	<0.001*

PPV: Positive predictive value, NPV: Negative predictive value, AUC: Area under the curve. *Significant as P value≤0.05.

Table 4: Role of trypsinogen 2 dipstick in prediction of acute pancreatitis

		CT		P value
		Group1	group2	
	Yes	11 (True positive)	3 (False positive)	<0.001*
Dip	No	1 (False negative)	89 (True negative)	
Sensitivity	Specificity	PPV	NPV	Accuracy
91.7%	96.7%	78.6%	98.9%	96.2%

PPV: Positive predictive value, NPV: Negative predictive value, AUC: Area under the curve. *Significant as value≤0.05

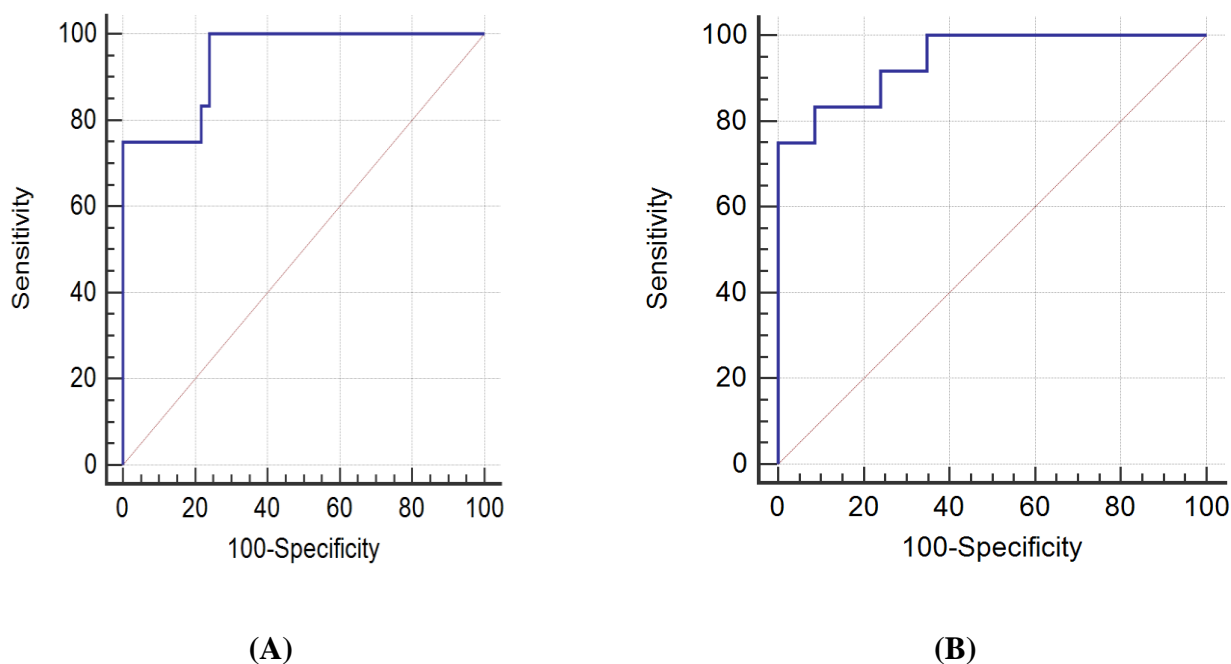


Figure 1: ROC curve of serum amylase (A) and serum lipase (B) in prediction of acute pancreatitis.

Discussion:

Including 104 patients who were suspected to have acute pancreatitis, we investigated the predictive value of urinary trypsinogen-2 (UT-2) dipstick compared to traditional markers, serum amylase and lipase, for the early diagnosis of acute pancreatitis.

In the current study, 12 (11.54%) patients suffered from acute pancreatitis. However, **Sethy et al.** (15) conducted a prospective study on 98 patients with acute severe pain abdomen suggestive of acute pancreatitis. They showed that 42% of patients had pancreatitis. On the other hand, **Yasuda et al.** (16) conducted a study in Japan on 94 patients. They showed that of these patients, 78 (82.9%) were diagnosed with acute pancreatitis and 16 (17.1%) with different diseases. The different study design as a multicentre and study area could explain these differences from our results.

In the current study, ALT, AST, ALP, total bilirubin and direct bilirubin were significantly higher in group I than group II. Creatinine was significantly higher in group I than group II. INR was insignificantly different between both groups. Intra-abdominal hypertension is very common in patients with acute pancreatitis and can lead to kidney impairment (17). The serum levels of ALT and AST are positively correlated with the severity of pancreatitis, and the serum levels of ALT and AST return to normal after pancreatitis is resolved (18). In agreement with our results, **Yasser et**

al. (19) carried out a study on 35 patients with acute pancreatitis (Group I) and 34 patients with other causes of acute abdomen (Group II). They observed that ALT, AST, total bilirubin and direct bilirubin were significantly higher in group I than group II. But, on contrary, they found that creatinine was insignificantly different between both groups. The different sample size could explain this difference from our results.

In this study, serum amylase and serum lipase were significantly higher in group I than group II. This came in line with **Yasser et al.** (19) who reported that serum amylase and serum lipase were significantly higher in acute pancreatitis patients group than other causes of acute abdomen group. Supporting our results, **Mayumi et al.** (20) performed a prospective multicentre study on 412 consecutive patients with acute abdominal pain. They noted that serum amylase and serum lipase were significantly higher in acute pancreatitis group than other diseases group.

Our results revealed that UT-2 was significantly higher in group I than group II. In the same line, **Yasser et al.** (19) found that UT-2 was significantly higher in acute pancreatitis patients group than other causes of acute abdomen group. In agreement with our results, **Mayumi et al.** (20) reported that UT-2 was significantly higher in acute pancreatitis group than other diseases group.

Acute gastritis was present in 12 (12.9%) patients. Biliary stones were present in 21 (22.58%) patients. Blunt trauma was present in 3 (3.23%) patients. Colonic diverticulosis was present in 12 (12.9%) patients. Esophagitis was present in 6 (6.45%) patients. Intestinal obstruction was present in 15 (16.13%) patients. Intestinal perforation was present in 10 (10.75%) patients. Urinary infection was present in 17 (18.28%) patients. Gastric ulcer was present in 1 (1.08%) patient. Abdominal pain was present in 3 (3.23%) patients. Infection was present in 4 (4.3%) patients. However, **Sethy et al.** (15) reported that the reasons behind the acute pain was acute gastritis in 50%, hollow viscus perforation in 11.7% and liver abscess in 3.9%. The different study area and sample size could explain this difference from our results. Also, **Yasser et al.** (19) illustrated that other causes of acute abdomen pain was intestinal obstruction in 5.88%, urinary tract infection in 2.94% and spontaneous bacterial peritonitis in 5.88 %.

In the current study, serum amylase can significantly predict acute pancreatitis (P value<0.001 and AUC=0.942) at cut off >597U/L with 83.3% Sensitivity, 78.3% specificity, 33.3% PPV and 97.3% NPV. Serum lipase can significantly predict acute pancreatitis (P value <0.001 and AUC=0.944) at cut off >620 U/L with 91.6% sensitivity, 76.1% specificity, 33.3% PPV and 98.6% NPV. In agreement with our results, **Zaki et al.** (21) carried out a cross-sectional study on 45 patients, 30 patients were

diagnosed as acute pancreatitis and 15 patients were not. They showed that the specificity of serum amylase, serum lipase was 73.3% for both. Supporting this result, **Sethy et al.** (15) showed that serum amylase and serum lipase can significantly predict acute pancreatitis as sensitivity, specificity, PPV and NPV of serum amylase was found to be 76.5%, 74.5%, 74.5% and 74.5% respectively and similarly, sensitivity, specificity, PPV and NPV of serum lipase was found to be 80.85%, 72.5%, 73.1% and 80.4% respectively.

Our results revealed that UT-2 can significantly predict acute pancreatitis (P value<0.001) with 91.7% sensitivity, 96.7% specificity, 78.6% PPV, 98.9% NPV and 96.2% accuracy. So, UT-2 can significantly predict acute pancreatitis better than serum amylase and serum lipase. This was in harmony with **Sethy et al.** (15) who illustrated that UT-2 can significantly predict acute pancreatitis with sensitivity and specificity of 91.48% and 94.11% respectively and PPV and NPV was found to be 93.47% and 92.30% respectively. This agreed by **Yasuda et al.** (16) who found that UT-2 dipstick test was a predictor of acute pancreatitis with sensitivity of 73.1%, specificity: 62.5%, positive and negative predictive values were 90.5% and 32.3%, respectively. In the study conducted by **Chandra et al.** (22) they found that sensitivity and specificity of Urine Trypsinogen-2 were found to be 97.2% and 93.75% respectively. In harmony with our results, **Mayumi et al.** (20) illustrated that the trypsinogen-2 dipstick test was positive in 107 of

156 patients with acute pancreatitis (sensitivity, 68.6%) and in 33 of 256 patients with nonpancreatic abdominal pain (specificity, 87.1%).

The study had several limitations, including being a single-center study, which may limit the generalizability of its findings, a small sample size that could lead to insignificant results, and the exclusion of patients with stage 3 or 4 renal disease and/or oliguria, which may have affected the overall conclusion.

Conclusion:

UT-2 dipsticks were a good predictor, even better than serum amylase and serum lipase for early diagnosis of acute pancreatitis with 91.7% sensitivity, 96.7% specificity and 96.2% accuracy. Moreover, acute pancreatitis was associated with higher ALT, AST, ALP, total bilirubin, direct bilirubin and creatinine.

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