URINARY AMYLASE AS A DIAGNOSTIC MARKER FOR ACUTE PANCREATITS – A PROSPECTIVE CASE-CONTROL STUDY

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Abstract

Background: Acute pancreatitis is commonly characterized by abdominal pain and elevated pancreatic enzyme levels. Diagnosis relies on clinical evaluation, laboratory tests, and imaging. Serum amylase is traditionally used but has a short half-life (10–12 hours), normalizing within 3–5 days, which may lead to false negatives in mild or late-presenting cases. In contrast, urinary amylase remains elevated for a longer duration, potentially offering improved diagnostic sensitivity. This study aims to compare the diagnostic utility of urinary amylase and serum amylase in acute pancreatitis.

Material and Methods: A prospective case-control study was conducted at the Department of General Surgery, SMIMS, Kanyakumari, Tamil Nadu, from April 2022 to June 2024. A total of 100 participants were enrolled using purposive sampling—50 diagnosed cases of acute pancreatitis and 50 healthy controls. After obtaining informed consent, serum amylase, serum lipase, and urinary amylase levels were measured in both groups.

Results: Most participants were aged 31–40 years. Mean ages were similar in both groups (cases: 45.03 ± 10.15; controls: 44.21 ± 9.87 years). Males predominated in the case group (82%). Elevated enzyme levels were observed in cases: serum amylase (690.65 ± 285.42 U/l), serum lipase (758.32 ± 210.76 U/l), and urinary amylase (1580.23 ± 450.98 U/l). ROC analysis showed urinary amylase had higher diagnostic reliability (AUC = 0.935) compared to serum amylase (AUC = 0.847).

Conclusion: Urinary amylase offers higher diagnostic sensitivity and prolonged detection, making it a valuable adjunct in diagnosing acute pancreatitis.

Keywords: Acute Pancreatitis**;** Urinary Amylase**;** Serum Amylase**;** Diagnostic Sensitivity.

Introduction

Acute pancreatitis is a prevalent condition typically marked by sudden abdominal pain. Despite its frequency, early and accurate diagnosis remains a challenge, especially in settings where rapid pancreatic enzyme testing is not readily available. According to the 2015 Japanese Guidelines for the Management of Acute Pancreatitis, serum lipase is recommended over serum amylase due to its higher specificity for pancreatic pathology [1]. Although serum amylase has

long been used as a diagnostic marker, it has limitations—most notably, a short half-life of about 10 to 12 hours, with levels usually returning to normal within three to five days [2]. This transient elevation can complicate diagnosis, particularly in patients with milder symptoms or delayed presentation.

Urinary amylase, on the other hand, may offer improved diagnostic value. Since amylase is cleared through the kidneys, urinary levels can remain elevated even after serum levels have declined [3]. This prolonged excretion can enhance the diagnostic window, potentially providing better sensitivity in identifying acute pancreatitis. During pancreatic inflammation, increased enzyme clearance into the urine may make urinary amylase a more consistent marker compared to its serum counterpart [4].

This study seeks to assess the diagnostic utility of urinary amylase relative to serum amylase in cases of acute pancreatitis. By evaluating their respective sensitivities and examining the correlation between the two, the research aims to determine whether urinary amylase could serve as a more reliable and non-invasive diagnostic alternative.

Methodology

A total of 100 participants were included in this study. Among them, 50 patients diagnosed with acute pancreatitis through clinical evaluation, imaging, and laboratory investigations were placed in the case group, while the remaining 50 healthy individuals formed the control group. All patients in the case group were admitted to the Department of Gastroenterology. Prior to enrollment, informed written consent was obtained from each participant. Upon admission, data collection was carried out according to standard operating procedures, which included a detailed medical history, comprehensive physical examination, and relevant serological and ultrasonographic (USG) investigations. As all cases were confirmed with acute pancreatitis at the time of admission, further tests were performed to identify the underlying etiology. Both groups (cases and controls) underwent assessment for serum lipase, serum amylase, and urinary amylase levels. These biochemical markers were compared between the two groups to evaluate the sensitivity and specificity of each diagnostic test. The estimations were performed using enzymatic methods on an automated biochemical analyzer, which also measured other parameters such as blood glucose, electrolytes, urea, creatinine, total protein, bilirubin, alkaline phosphatase (SGPT), and lipid profile. A commercially available diagnostic kit was used for these assays.

In addition, hematological parameters were evaluated using a five-part hematology analyzer. All participants were scheduled for an abdominal USG scan. Patients with uncontrolled diabetes, hypertension, chronic kidney disease, or those who declined to participate were excluded from the study. Data analysis was performed using SPSS software, version 20 (SPSS Inc., Chicago, IL). Continuous variables were expressed as mean ± standard deviation, and comparisons between the case and control groups were made using the unpaired Student's t-test. For categorical variables, the Chi-square test or Fisher's exact test was used, and the results were presented as percentages. A p-value of less than 0.05 was considered statistically significant.

RESULTS
Table 1: Age Distribution of Study participants

Characteristics	Group

Age Group (In years)	Case group (n=50)	Control group (n=50)
< 20	3 (6%)	1 (2%)
21-30	12 (24%)	11 (22%)
31-40	23 (46%)	23 (46%)
41-50	6 (12%)	7 (14%)
>50	6 (12%)	8 (16%)
Gender		
Male	41 (82%)	19 (38%)
Female	9 (18%)	31 (62%)

Table 1 shows that the majority of participants in both the case and control groups are aged 31-40 years, making up 46% of each group. The age distribution is relatively balanced between the groups across all age categories. The mean age is similar between the case group (45.03 ± 10.15 years) and the control group (44.21 ± 9.87 years).

Table 2: Baseline and USG Characteristics among Study participants

Characteristics	Case group (n=50)	Control group (n=50)
Symptoms		
Pain abdomen	50 (100%)	0 (0%)
Vomiting	40 (80%)	0 (0%)
Habits		
Alcohol	38 (76%)	10 (20%)
Smoking	12 (24%)	11 (22%)
Co-morbidities		
DM	3 (6%)	4 (8%)
HTN	2 (4%)	3 (6%)
IHD	1 (2%)	2 (4%)
Obesity	6 (12%)	5 (10%)
USG Findings		
Diffusely enlarged and hypoechoic pancreas	27 (54%)	0 (0%)
Diffusely enlarged and hypoechoic pancreas with cholelithiasis	5 (10%)	0 (0%)
Pancreas obscured by bowel gas	18 (36%)	0 (0%)

Table 3 outlines the baseline and ultrasound (USG) characteristics of study participants. The case group exhibits significant abdominal symptoms, with 50(100%) reporting abdominal pain and 40(80%) experienced vomiting. Alcohol consumption is notably higher in the case group 38(76%) compared to the control group 10((20%), while smoking rates are similar (24% in the case group vs. 22% in the control group).

Co-morbidities show lower prevalence in the case group for diabetes mellitus 3((6%), hypertension 2((4%), and ischemic heart disease 1(2%) compared to the control group. Obesity rates are comparable (12% in the case group vs. 10% in the control group).

USG findings indicate that 27(54%) of the case group show a diffusely enlarged and hypoechoic pancreas, with 5(10%) also having cholelithiasis and 18(36%) obscured by bowel gas. In contrast, no abnormal findings were reported in the control group, highlighting a significant difference in pancreatic health between the two groups.

Table 4: Diagnostic markers of acute pancreatitis in both groups

| Diagnostic markers	Cases Group (n=50)	Control Group (n=50)	p-value
Serum amylase (U/l)	690.65±285.42	45.91±65.78	**0.001**
Serum lipase (U/l)	758.32±210.76	53.81±40.45	**0.001**
Urinary amylase (U/l)	1580.23±450.98	303.65±120.12	**0.001**

Table 4 presents the diagnostic markers of acute pancreatitis in both the case and control groups. The case group shows significantly elevated levels of serum amylase (690.65 ± 285.42 U/l), serum lipase (758.32 ± 210.76 U/l), and urinary amylase (1580.23 ± 450.98 U/l) compared to the control group, which has levels of 45.91 ± 65.78 U/l for serum amylase, 53.81 ± 40.45 U/l for serum lipase, and 303.65 ± 340.12 U/l for urinary amylase. All comparisons yield a p-value of 0.001, indicating highly significant differences between the two groups, thereby confirming the diagnostic utility of these markers in identifying acute pancreatitis.

Table 5: ROC curve analysis of diagnostic markers

Diagnostic markers	Cut-off	Sensitivity (%)	Specificity (%)	+LR	-LR	AUC	P-value
Serum amylase (U/l)	>72	100	93.85	15.95	0.0	0.847	**0.001**
Serum lipase (U/l)	>95	98.56	96.21	19.78	0.002	0.948	**0.005**
Urinary amylase (U/l)	>315	97.32	92.45	10.11	0.005	0.935	**0.002**

Table 5 presents the ROC curve analysis for diagnostic markers of acute pancreatitis. Serum Amylase demonstrates a cut-off value of >72 U/l, achieving a sensitivity of 100% and specificity of 93.85%, with a positive likelihood ratio (+LR) of 15.95, a negative likelihood ratio (-LR) of 0.0, and an AUC of 0.847 (p=0.001). Serum Lipase, with a cut-off of >95 U/l, shows a sensitivity of 98.56% and a specificity of 96.21%, resulting in a +LR of 19.78, -LR of 0.002, and the highest AUC of 0.948 (p=0.005). Urinary Amylase, set at a cut-off of >315 U/l, exhibits a sensitivity of 97.32% and specificity of 92.45%, along with a +LR of 10.11, -LR of 0.005, and an AUC of 0.935 (p=0.013).

Figure 1: ROC Curves for Diagnostic Markers
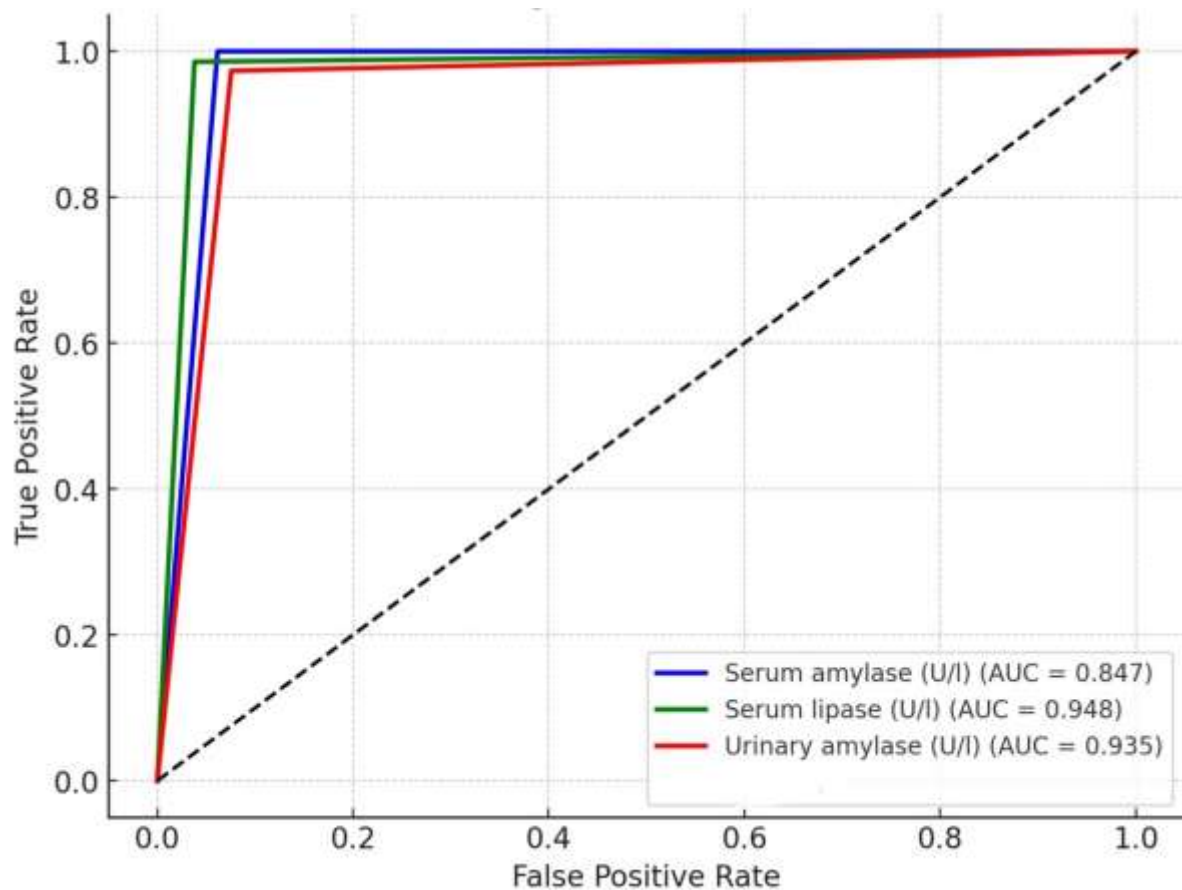
In Figure 1, the Receiver Operating Characteristic (ROC) curves illustrate the diagnostic performance of three biomarkers: Serum Amylase, Serum Lipase, and Urinary Amylase. Among these, Serum Lipase demonstrates the highest diagnostic accuracy, with an Area Under the Curve (AUC) value of 0.948. Notably, Urinary Amylase exhibits superior diagnostic efficacy when compared to Serum Amylase, as reflected by its AUC value of 0.935 versus 0.847, respectively. The elevated AUC value for Urinary Amylase indicates its enhanced capability to distinguish between true positive and false positive cases, thereby establishing it as a more reliable diagnostic marker relative to Serum Amylase. This finding underscores the potential utility of Urinary Amylase in clinical diagnostics

DISCUSSION

In India, acute pancreatitis constitutes a considerable proportion of daily hospital admissions, primarily due to high rates of alcohol consumption and gallstone disease (cholelithiasis) [5]. The condition can arise from multiple etiologies, though alcohol use and cholelithiasis together contribute to nearly 80% of cases [5]. Various biomarkers and clinical scoring systems are employed to assess disease severity and guide treatment strategies. However, many of these biomarkers lack specificity and may also be elevated in other acute inflammatory conditions. In clinical practice across India, serum amylase and lipase are commonly used together for diagnosis. Despite this, the search for affordable, reliable, and easily reproducible diagnostic markers continues. Urinary amylase has emerged as a promising candidate—it is

simple to measure and may offer greater specificity for acute pancreatitis.

In the present study, the majority of patients diagnosed with acute pancreatitis were between 31–40 years of age, with a mean age of 45.03 ± 10.15 years. These findings are in line with the observations of Kandasami et al., [6] who reported a mean age of 43.5 years (±14.7), although Chauhan et al. noted a slightly older affected population with a mean age of 54 years, most commonly in the 50–59year age group. The age distribution in the current study supports the trend that acute pancreatitis primarily affects middle-aged adults.

A notable male predominance was observed in the present study (82%), which is consistent with earlier studies by Chauhan et al. and Kandasami et al., [6] who also reported higher prevalence among males. This is likely associated with lifestyle-related risk factors, particularly alcohol consumption. In this study, alcohol was reported as a major contributing factor by 76% of the cases, significantly higher than the 47.7% reported by Kandasami et al., [6] highlighting a strong correlation between alcohol use and acute pancreatitis in the studied population.

Clinically, all patients in the present study reported abdominal pain (100%), and 80% experienced vomiting. These findings are comparable to those of Nehal Naik et al., [7] who reported abdominal pain in 100% of patients, vomiting in 66%, and abdominal distension in 30%. This consistency reinforces that abdominal pain remains the most prominent presenting symptom in acute pancreatitis.

Ultrasound findings in the present study revealed that 54% of patients had a diffusely enlarged and hypoechoic pancreas, 10% had cholelithiasis, and 36% had obscured views due to bowel gas. This is comparable to the findings of Kalaiventhan et al., [8] who observed that 50.9% of individuals with elevated amylase levels had positive USG findings, and even among those with normal amylase, 30% showed ultrasonographic evidence of pancreatitis. These results emphasize the diagnostic value of imaging, particularly in cases where biochemical markers may be inconclusive.

In the present study, all three biochemical markers—serum amylase, serum lipase, and urinary amylase—were significantly elevated in patients with acute pancreatitis compared to controls ($p < 0.001$). Serum lipase demonstrated the highest diagnostic accuracy (AUC = 0.948), followed closely by urinary amylase (AUC = 0.935) and serum amylase (AUC = 0.847). Sensitivity and specificity for serum amylase were observed to be 100% and 94.56%, respectively, aligning well with the findings of Kemppainen et al., [9] who reported 85% sensitivity and 91% specificity, and Gumaste et al., [10] who found 72% sensitivity and 99% specificity. Similarly, serum lipase in the present study showed 98.82% sensitivity and 96.53% specificity, which is consistent with the results of Gumaste et al. [10] (100% sensitivity, 99% specificity) and Kylanpaa-Back et al. [11] (55% sensitivity, 99% specificity), further supporting the robustness of lipase as a diagnostic marker. Urinary amylase in this study exhibited 97.32% sensitivity and 91.47% specificity, outperforming results from Kemppainen et al. [9] (83% and 88%) and Treacy et al. (62% and 97%) [12].These comparisons suggest that while serum lipase remains the most accurate single test, urinary amylase offers comparable diagnostic value and may be particularly useful in delayed presentations due to its prolonged elevation and ease of collection.

Overall, the present study confirms the diagnostic utility of conventional markers such as serum amylase and lipase while supporting the inclusion of urinary amylase as a valuable, sensitive, and specific tool in the evaluation of acute pancreatitis.

This single-center study had a limited sample size and used purposive sampling, which may affect generalizability. Timing of sample collection was not standardized, and renal function, which can influence urinary amylase levels, was not fully controlled. Larger, multicentric studies are needed for validation.

CONCLUSION

The present study highlights that while serum amylase remains a standard diagnostic marker for acute pancreatitis, its limitations in mild or late-presenting cases necessitate alternative approaches. Urinary amylase demonstrated high sensitivity and specificity, comparable to serum lipase, and offers the advantage of prolonged elevation, making it a valuable non-invasive adjunct in diagnosis. Incorporating urinary amylase into routine diagnostic evaluation may enhance the accuracy and timeliness of acute pancreatitis detection.

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