# TO EVALUATE THE EFFICACY OF URINARY TRYPSINOGEN 2 DIPSTICK TEST IN DIAGNOSING ACUTE PANCREATITIS

*Prem Anandh[1], Arcot Rekha[2]*

*[1]Junior Resident, Department of General Surgery, Sri Ramachandra Medical College and Research Institute, SRU, Chennai.*
*[2]Professor, Department of General Surgery, Sri Ramachandra Medical College and Research Institute, SRU, Chennai.*

**ABSTRACT**

**BACKGROUND**

Pancreatitis is a common cause of abdominal pain in the emergency room. Serum amylase and lipase are the initial screening investigations. A rapid urine analysis by a dipstick to detect urinary trypsinogen is a good screening test.

**MATERIALS AND METHODOLOGY**

This study was conducted after obtaining the Institutional Ethics Committee (IEC) clearance, Reference No.: CSP - MED/14/FEB12/50. Informed consent was obtained from all study participants and ICH/GCP guidelines were followed. The present prospective study was done during the period of June 2013 to October 2015, which involved a group of 98 patients with upper abdominal pain (Reporting within 36 hours of onset of pain) who came to the Department of Surgery of Sri Ramachandra Medical College and Research Institute.

**RESULTS**

A total of 98 consecutive patients with upper abdominal pain who fulfilled the inclusion criteria and exclusion criteria were enrolled in the study during the period of June 2013 - October 2015. When we analysed the patients with upper abdominal pain we found that in the age group 21-30, there were 22 patients (22.9%); in 31-40 years, there were 28 patients (29.2%); in 41-50 years, there were 17 patients (17.7%); in 51-60 years, there were 18 patients (18.8%); and in between 61-70 years, there were 11 patients (11.5%) of study group (1, 2).

**CONCLUSIONS**

The analysis of the demographics of our study showed that 40.8% of acute upper abdominal pains were due to acute pancreatitis and 59.2% were non-pancreatic in origin. Male Patients accounted for 75.0% and 65.5% respectively in the acute pancreatitis and non-pancreatic groups. In both acute pancreatitis and non-pancreatic groups, major clustering of patients was seen in the age group of 31-40 yrs.

**KEYWORDS**

Urinary Trypsinogen, Pancreatitis, Dipstick Assay.

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**INTRODUCTION:** The urinary trypsinogen-2 dipstick test detected acute pancreatitis more accurately than quantitative serum or urinary amylase determinations, and its accuracy was similar to that of the quantitative assay for urinary trypsinogen-2. The detection limit of the trypsinogen-2 test strip, about 50 ng per millilitre, appears to provide a good balance between sensitivity (94 percent) and specificity (95 percent). We wished to check if the same pattern is observed in patients in the Indian subcontinent.

**MATERIALS AND METHODOLOGY:** This study was conducted after obtaining the Institutional Ethics Committee (IEC) clearance, Reference No.: CSP-MED/14/FEB12/50. Informed consent was obtained from all study participants and ICH/GCP guidelines were followed.

The present prospective study was done during the period of June 2013 to October 2015, which involved a group of 98 patients with upper abdominal pain (Reporting within 36 hours of onset of pain) who came to the Department of Surgery of Sri Ramachandra Medical College and Research Institute.

**Inclusion Criteria:** Patients (More than 18 years of age) who came to our hospital with upper abdominal pain within 36 hours of onset of pain were included in the study.

**Exclusion Criteria:** We excluded patients who were previously treated for similar illness, recurrent pancreatitis, Pregnant and lactating mothers, known renal disease patients and those who were not willing to be part of the study.

**Methodology:** All patients with acute abdominal pain who met the inclusion and exclusion criteria were taken into the study after signing an informed written consent. Detailed

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*Corresponding Author:*
*Dr. Arcot Rekha,*
*#769, 9th ST, Annanagar, West Extension,*
*Chennai-600116.*
*E-mail: rekha_a@yahoo.com*
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history was taken and thorough general physical examination was done at the onset of the study.

Full clinical assessment (History taking and Clinical Examination), Laboratory investigations including (Complete blood count (CBC), Bilirubin (Total and Direct), ALT, AST, alkaline phosphatase (ALP), Urea, Creatinine, Serum Calcium, LDH, Serum Amylase, Serum Lipase, Urinary, Trypsinogen - 2 dipstick test (UT2DT). Abdominal ultrasonography (USG) and computerised tomography (CT) was done for all patients with special emphasis on the pancreas and biliary system to establish the diagnosis. Sensitivity, Specificity, PPV and NPV of these tests in diagnosing acute pancreatitis were calculated.

**Specimen Collection:** A sample of 5 mL venous blood was collected at admission from each patient, the samples were left to clot and then centrifuged at 3000 rpm for 5 minutes. The serum was then separated & stored at −20°C for measuring amylase and lipase. Urine sample was taken at the time of admission for trypsinogen-2 determination by UTDT.

**Trypsinogen - 2 Measurements:** The dipstick test for urinary trypsinogen-2 is an immunochromatographic test. After the test strip has been dipped into the urine sample, trypsinogen-2 is bound to monoclonal-antibody– labelled blue latex particles, which migrate across a nitrocellulose membrane with a zone containing another antibody specific for another epitope on trypsinogen-2. At trypsinogen-2 concentrations higher than 50 ng per millilitre, a blue line develops in this zone. A positive result on the test strip remains visible for at least one year. A control line is used to indicate proper functioning of the strip. If the control line is undetectable the assay needs to be repeated. The tip of the strip was immersed into a urine-containing vial and was held for 20 sec. before being completely taken out of the vial. The strip was then kept at room temperature for 5 min.

Figure 1: Test strip showing negative result (Only control Line is seen). Hyperamylasaemia was defined as an increase of serum amylase of greater than three times the upper limit of normal (300 U/L).

Hyperlipasaemia was defined as an increase of serum lipase of greater than three times the upper limit of normal (180 U/L). The criteria for diagnosis of acute pancreatitis were two of the following three features:

1. Abdominal pain characteristic of acute pancreatitis.
2. Serum amylase and/or lipase ≥3 times the upper limit of normal.
3. Characteristic findings on CT scan.

**STATISTICAL ANALYSIS:** The statistical analysis was carried out with IBM SPSS Version - 20 (Chicago, IL, USA). Categorical data is presented as actual numbers and percentages. Categorical variables were analysed with Chi square test. Continuous variables are presented as Mean (SD). For normally distributed data between groups, analyses were done by unpaired t test. Abnormally distributed data was analysed by using non-parametric Mann Whitney U test.

For statistical significance, a two tailed probability value of less than 0.05 was considered. Sensitivity, specificity, positive predictive value, and negative predictive value of the tests were calculated and compared. For serum concentrations of amylase and lipase, a threefold increase in the reference values recommended by our laboratory were selected as cut-off values. Using these cut-off points, the sensitivity, specificity, positive (PPV) and negative predictive value (NPV) in establishing the diagnosis of AP were calculated.

**RESULTS:** A total of 98 consecutive patients with upper abdominal pain who fulfilled the inclusion criteria and exclusion criteria were enrolled in the study during the period of June 2013-October 2015. When we analysed the patients with upper abdominal pain, we found that in the age group 21-30 there were 22 patients (22.9%); in 31-40 years, there were 28 patients (29.2%); in 41-50 years, there were 17 patients (17.7%); in 51-60 years, there were 18 patients (18.8%); and in between 61-70 years, there were 11 patients (11.5%) of study group.[1,2] Table 1 depicts the age distribution of cases.

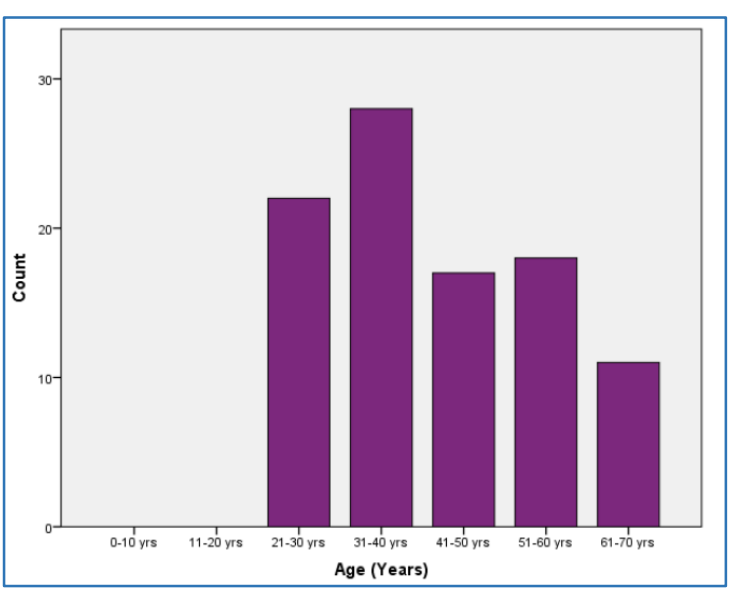


***Table 1: Age (years) Distribution of Cases***

**Gender Distribution of Cases:** When we looked at the gender distribution of upper abdominal pain we found that male constituted to 68 patients which is 69.4%, female constituted to 30 which is 30.6%.[3,4]

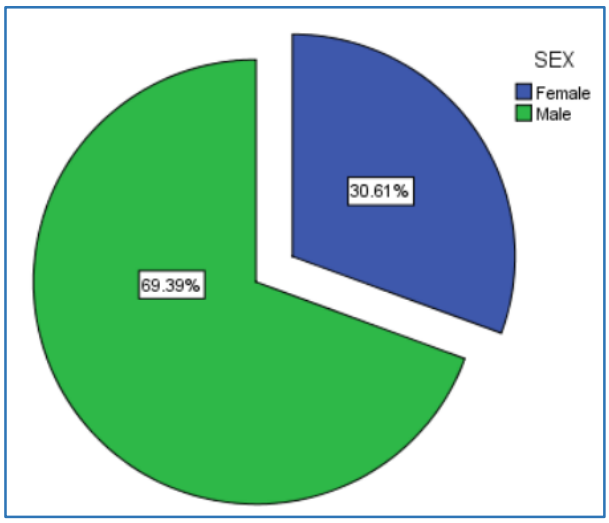


***Fig. 1: Gender Distribution***

A clinical diagnosis of acute pancreatitis was made based on two of the following three features:

1. Abdominal pain characteristic of acute pancreatitis.
2. Serum amylase and/or lipase ≥ 3 times the upper limit of normal.
3. Characteristic findings on CT scan.

| Parameters | Acute Abdominal pain (98) | |
|---|---|---|
| | Acute Pancreatitis (AP) | Non-Pancreatic (NP) |
| | 40 (40.8%) | 58 (59.2%) |

***Table 2: Distribution of Cases among Groups***

40 patients were diagnosed as acute pancreatitis (AP) which accounted for 40.8% and remaining 58 patients were diagnosed as abdominal pain due to non-pancreatic causes which accounted for 59.2% (NP) as shown in Table 2.

| Age (Years) | Group | | | |
|---|---|---|---|---|
| | Acute Pancreatitis | | Non-Pancreatic | |
| | N | N% | N | N% |
| 0-10 yrs. | 0 | 0.0% | 0 | 0.0% |
| 11-20 yrs. | 0 | 0.0% | 0 | 0.0% |
| 21-30 yrs. | 8 | 21.1% | 14 | 24.1% |
| 31-40 yrs. | 10 | 26.3% | 18 | 31.0% |
| 41-50 yrs. | 9 | 23.7% | 8 | 13.8% |
| 51-60 yrs. | 5 | 13.2% | 13 | 22.4% |
| 61-70 yrs. | 6 | 15.8% | 5 | 8.6% |

***Table 3: Age (Years) Distribution of Cases among Groups***

When we analysed the patients with acute pancreatitis, we found that in the age group 21-30, there were 8 patients (21.1%); in age group 31-40, there were 10 patients (26.3%); in age group 41-50, there were 9 patients (23.7%); in age group 51-60, there were 5 patients (13.2%); in age group of 61-70, there were 6 patients (15.8%). When we analysed the patients with abdominal pain not due to pancreatitis, we found that in the age group 21 – 30, there were 14 patients (24.1%); in age group 31–40, there were 18 patients (31.0%); in age group 41-50, there were 8 patients (13.8%); in age group 51-60, there were 13 patients (22.4%); in age group of 61-70, there were 5 patients (8.6%) as shown in Table 3.

**Gender Distribution of Cases among Groups:** When we looked at the gender distribution of patients with non-pancreatic abdominal pain, we found that males constituted 38 patients which is 65.5%, females constituted 20 which is 34.5%. In acute pancreatitis, we found that males constituted 30 patients which is 75.0%, females constituted 10 patients which is 25.0% as shown in Table 4.

| | | Group | | | |
|---|---|---|---|---|---|
| | | Non-Pancreatic | | Acute Pancreatitis | |
| | | Count | Column N% | Count | Column N% |
| Gender | Female | 20 | 34.5% | 10 | 25.0% |
| | Male | 38 | 65.5% | 30 | 75.0% |

***Table 4: Gender Distribution of Cases among Groups***

Acute pancreatitis is caused by inappropriate activation of trypsin, leading to pancreatic autodigestion and serum amylase and serum lipase are released into the blood stream. Usually, 3 fold elevation than normal value is suggestive of acute pancreatitis.[5,6,7] When we analysed the S. amylase and S. Lipase in our study population, we found S Amylase levels were higher in patients with Acute Pancreatitis group [794.2(698.5)] as compared to the other group [77.3(75.7)], this was statistically significant (P= <0.0001). S Lipase levels were higher in patients with Acute Pancreatitis group [968.0(1132.8)] as compared to the other group [41.1(30)], this was statistically significant (p=<0.0001) as shown in Table 5.

| Parameters | Group | | | | P |
|---|---|---|---|---|---|
| | Non-Pancreatic (58) | | Ac Pancreatitis (40) | | |
| | Mean | SD | Mean | SD | |
| S. Amylase (IU/L) | 77.3 | 75.7 | 794.2 | 698.5 | <0.0001 |
| S. Lipase (IU/L) | 41.1 | 30.0 | 968.0 | 1,132.8 | <0.0001 |

***Table 5: Mean S. Amylase and S. Lipase Distribution among Groups***

Hyperbilirubinaemia with altered ALP and AST are seen in most of acute pancreatitis patients. When we analysed in our study group, we found that mean total bilirubin levels were higher in patients with acute pancreatitis [2.5(2.1)] as

compared to the other group [1.3 (1.2)] mg/dL, this was statistically significant (p=<0.0001). Mean direct bilirubin levels were higher in patients with Acute pancreatitis [1.2(1.1)] as compared to non-pancreatic group [0.7 (0.9)] mg/dL, this was also statistically significant [p=0.007] as shown in Table 6.

| Parameters | Group | | | | P |
|---|---|---|---|---|---|
| | Non-Pancreatic (58) | | Ac Pancreatitis (40) | | |
| | Mean | SD | Mean | SD | |
| Total Bilirubin (mg/dL) | 1.3 | 1.2 | 2.5 | 2.1 | <0.0001 |
| Direct Bilirubin (mg/dL) | 0.7 | 0.9 | 1.2 | 1.1 | 0.007 |

***Table 6: Distribution of Mean Bilirubin Level among Groups***

| Parameters | Group | | | | P |
|---|---|---|---|---|---|
| | Non-pancreatic (58) | | Ac Pancreatitis (40) | | |
| | Mean | SD | Mean | SD | |
| AST (IU/L) | 69.3 | 126.0 | 138.8 | 219.0 | 0.05 |
| ALT (IU/L) | 63.6 | 93.3 | 149.6 | 292.7 | 0.039 |

***Table 7: Distribution of Mean AST/ALT Level among Groups***

Mean AST was higher in patients with Acute pancreatitis group [138.8(219)] as compared to other group [69.3(126)].

This was statistically significant (p=0.05). Mean ALT was higher in Acute Pancreatitis group [149.6(292.7)] as compared to Non-Pancreatic group [63.6 (93.3)] IU/L, This was statistically significant (p=0.04) as shown in Table 7.

**Distribution of Renal Parameters Among Groups:** Serum creatinine and BUN are known markers of assessing severity, when we assessed those markers in our study patients, we found mean Serum creatinine did not significantly vary between Acute Pancreatitis [1.9(3.6)] and Non-Pancreatic group [1.2(1.6)] mg/dL, with (p=0.23). Mean BUN also did not significantly vary between Acute Pancreatitis. [13.3(9.8)] and Non-Pancreatic group [15.6(10.4)] mg/dL, with p=0.26 as seen in Table 8.

| Parameters | Group | | | | P |
|---|---|---|---|---|---|
| | Non-Pancreatic (58) | | Ac Pancreatitis (40) | | |
| | Mean | SD | Mean | SD | |
| Serum Creatinine (mg/dL) | 1.2 | 1.6 | 1.9 | 3.6 | 0.234 |
| BUN (mg/dL) | 15.6 | 10.4 | 13.3 | 9.8 | 0.263 |

***Table 8. Distribution of Renal Parameters Between the Groups***

When we analysed the distribution of the white blood cell counts (as shown in Table 9), we found that the mean total count of WBC was significantly high in AP group compared to NP group[14752(4612) vs. 10482 (3863) mm3/dl, p=<0.0001]. Polymorphs were also significantly high in AP group compared to NP group. [82.9 (7.7%) vs. 68.9 (13.2%), p=<0.0001]. Fig 2 and Fig 3 shows the distribution of the total white cell count and the polymorphs in the two groups.[5,6,7]

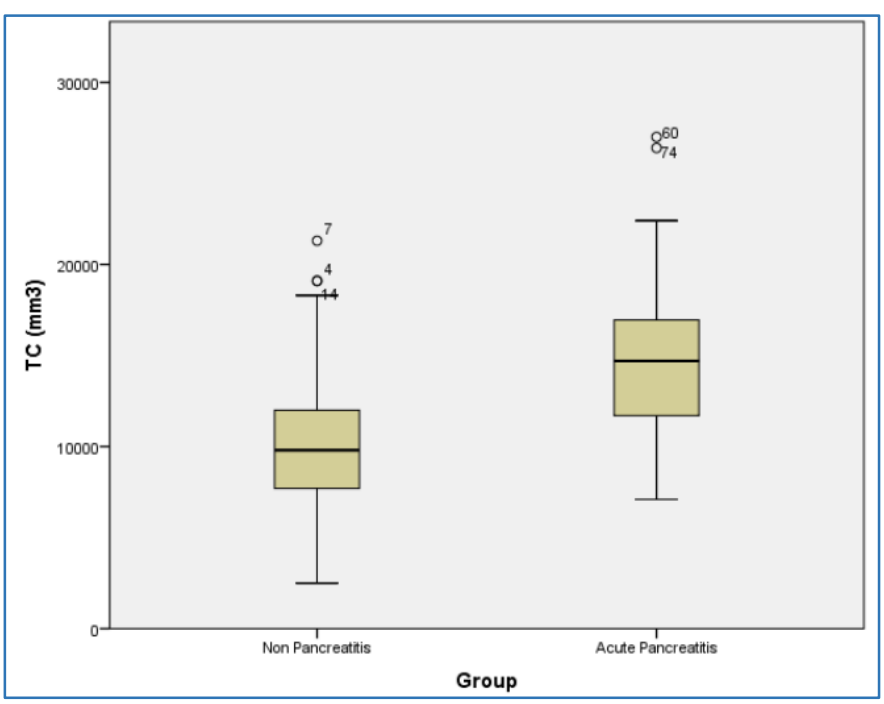


***Fig. 2: Distribution of WBC between the groups***

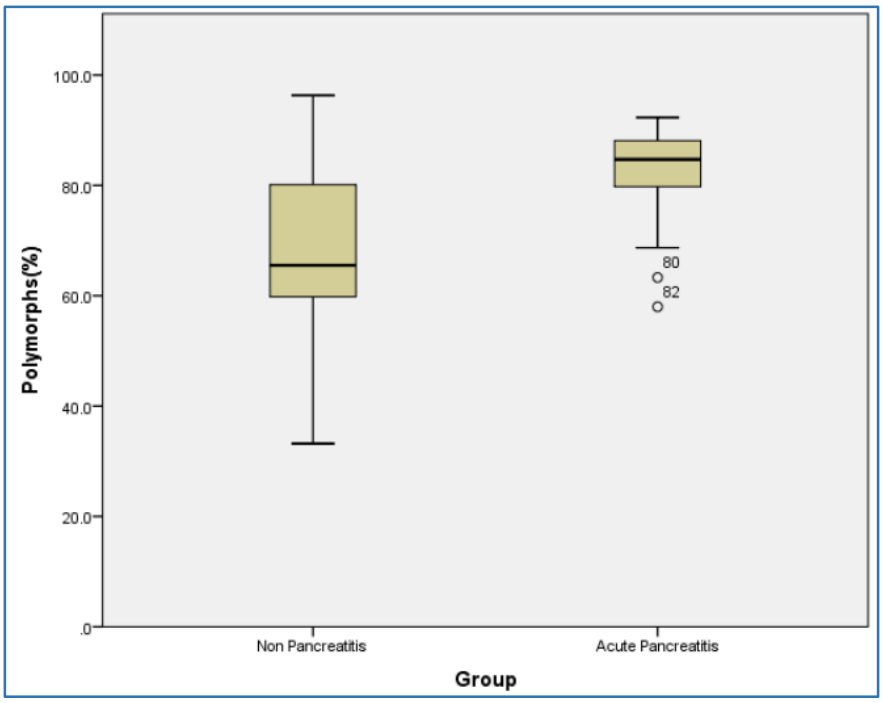


***Fig. 3: Distribution of Polymorphs between the Groups***

| Parameters | Group | | | | P |
|---|---|---|---|---|---|
| | Non-pancreatic (58) | | Ac Pancreatitis(40) | | |
| | Mean | SD | Mean | SD | |
| Total Count of WBC ($mm^3$/dL) | 10,482 | 3,863 | 14,752 | 4,612 | <0.0001 |
| Polymorphs (%) | 68.9 | 13.2 | 82.9 | 7.7 | <0.0001 |

***Table 9: Show the White Cell Count Distribution***

When we analysed the patients with abdominal pain not due to pancreatitis, we found the following distribution of aetiology.

| Cause | Count | Column N% |
|---|---|---|
| Gastritis | 18 | 31.00% |
| Acute calculous Cholecystitis | 13 | 22.40% |
| Liver disease | 8 | 13.80% |
| Acute acalculous cholecystitis | 5 | 7.60% |
| Acute Gastroenteritis | 4 | 6.90% |
| Abdominal Malignancy | 4 | 6.90% |
| Gall Bladder Polyp | 3 | 5.20% |
| Gastro-Intestinal perforation | 2 | 3.40% |
| Abdominal TB | 1 | 1.70% |

***Table 10: Aetiology of Acute Abdominal Pain in NP Group***

In the Non-pancreatitis group (Fig 4), acute gastritis accounted for 31% of patients, acute calculous cholecystitis accounted for 22.4% of patients, hepatic disease accounted for 13.80% of patients, acute acalculous cholecystitis, accounted for 6.9% of patients, abdominal malignancy constituted 6.90% of patients, acute gastroenteritis accounted for 6.9% of patients, gall bladder polyps accounted for 5.2% of patients, gastrointestinal perforation accounted for 3.40% of patients and abdominal tuberculosis accounted for 1.7% of patients as shown in Table 10.

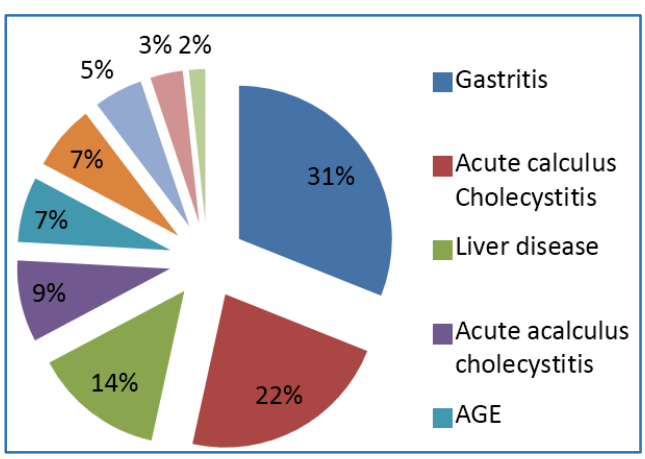


***Fig. 4a: Shows the Causes of Abdominal Pain not Due to Pancreatitis***

As shown in Fig. 5, when we analysed the patients with abdominal pain due to pancreatitis, we found the following distribution of aetiology. In AP group, alcoholism accounted for nearly half of the pancreatitis group (45%), acute calculous cholecystitis was the second most important cause which accounted to 22.5%, followed by idiopathic which was 10%, post ERCP constituted 7.5%, drug induced were 5%, increased TGL also constituted 5%, infection and pancreatic divisum both contributed 2.5% each.

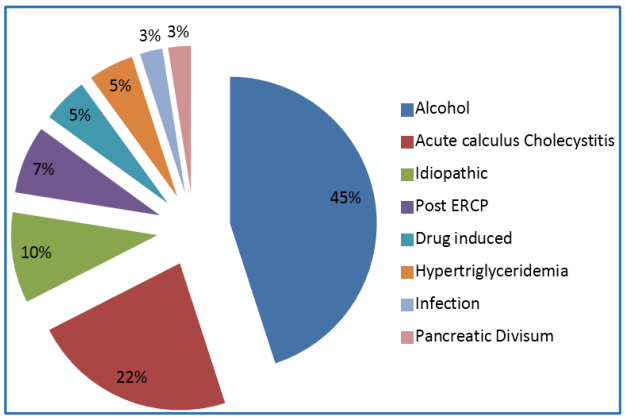


***Fig. 4b: Aetiology of Acute Pancreatitis***

At the end of data acquisition, we attempted to calculate the sensitivity and specificity of the various investigations.

| Test | | Acute Pancreatitis | Non-Pancreatic |
|---|---|---|---|
| S Amylase | Positive | 36 | 12 |
| | Negative | 4 | 46 |

***Table 11a: 2X2 to Evaluate Sensitivity, Specificity, PPV & NPV***

We found the sensitivity of S. Amylase to be 90% and its specificity to be 79.3%, its positive predictive value to be 75% and negative predictive value to be 92%, Table 11a.

| | | | |
|---|---|---|---|
| S Lipase | Positive | 37 | 6 |
| | Negative | 3 | 52 |

***Table 11b: To calculate the Sensitivity, Specificity of Lipase***

Sensitivity of S. lipase was 92.5% and its specificity was 89.7%. Its positive predictive value was 86% and negative predictive value was 94.5% (Table 11b). Similarly, we plotted a 2x2 Table to calculate the sensitivity, specificity and predictive value for ultrasound and CT.

| | | | |
|---|---|---|---|
| USG | Positive | 28 | 9 |
| | Negative | 12 | 49 |
| CT | Positive | 33 | 3 |
| | Negative | 2 | 55 |

***Table 12: Shows the Table used for USG and CT***

Sensitivity of USG was 70% and its specificity was 84.5%. Its positive predictive value was 75.7% and negative predictive value was 80.3%. Sensitivity of CT Abdomen was 94.3% and its specificity was 94.8%. Its positive predictive value was 91.7% and negative predictive value was 96.5%.

In acute pancreatitis, rapid diagnosis and early treatment are of importance for clinical outcome. Urinary trypsinogen-2 dipstick test has been suggested as a promising diagnostic marker.[8,9] When we analysed our study, we found sensitivity of UTDT was 90% and its specificity was 84.5%. Its positive predictive value was 80.0% and negative predictive value was 92.5% as shown in Table 13.

| Test | | Acute Pancreatitis | Non-Pancreatic |
|---|---|---|---|
| UTDT | Positive | 36 | 9 |
| | Negative | 4 | 49 |

***Table 13: Shows the Analysis of the Urinary Trypsinogen Dipstick Test***

| Test | Sensitivity | Specificity | PPV | NPV |
|---|---|---|---|---|
| S Amylase ≥3 ULN | 90 | 79.3 | 75.0 | 92.0 |
| S. Lipase≥3 ULN | 92.5 | 89.7 | 86.0 | 94.5 |
| USG | 70 | 84.5 | 75.7 | 80.3 |
| CT | 94.3 | 94.8 | 91.7 | 96.5 |
| UTDT | 90 | 84.5 | 80.0 | 92.5 |

***Table 13b: Is a Graphic Representation of all the Parameters***

ROC allows to create complete sensitivity/specificity report. The ROC is a fundamental tool for diagnostic test evaluation. In a ROC, the true positive rate (Sensitivity) is plotted in function of the false positive rate (100-Specificity) for different cut-off points of a parameter.[10,11] Each point on the ROC represents a sensitivity/specificity pair corresponding to a particular decision threshold. The area under the ROC curve (AUC) is a measure of how well a parameter can distinguish between two diagnostic groups (Diseased/Normal). Shown in Figure 5.

| Area Under the Curve | |
|---|---|
| Test Result Variable(s) | Area |
| S Amylase | 0.868 |
| S Lipase | 0.920 |
| USG | 0.765 |
| CT | 0.946 |
| UTDT | 0.880 |

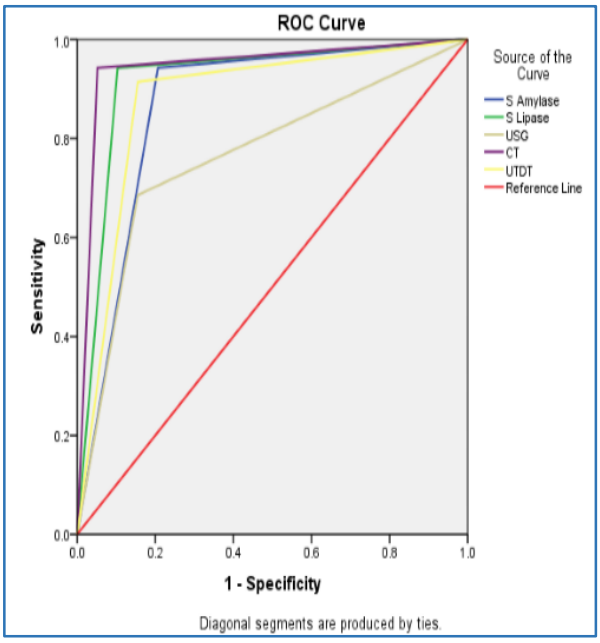


***Fig. 5***

**DISCUSSION:** Acute pancreatitis (AP) is an inflammatory disease characterised by steady, acute abdominal pain of varying severity, often radiating from the epigastrium to the back. Its presentation ranges from a self-limiting mild disorder to a more severe and fulminant disease. Severe acute pancreatitis accounts for 30% of all deaths related to pancreatitis. The incidence of AP is increasing progressively with a corresponding increase in the incidence of its risk factors. The most common cause of AP is gallstones (40 – 70%) and alcohol (25 – 35%) (183 – 185). However, in our study, most common cause of AP was alcoholism (45%) followed by gallstones (22%). This might be due to higher number of male patients recruited in the AP group. In 10% of patients with acute pancreatitis, the aetiology was Idiopathic. Other causes were drug induced, post ERCP, pancreatic divisum, and increased TGL. In NP group, the common causes for acute abdominal pain was acute gastritis, acute calculous cholecystitis, hepatic disease, acute acalculous cholecystitis, and acute gastroenteritis.

An ideal laboratory test in the evaluation of a patient with acute pancreatitis (AP) should accurately establish the diagnosis of AP and identify the aetiology. None of the tests available today meet all these criteria, and presently there is no biochemical test that can be considered the "Gold Standard" for the diagnosis and assessment of aetiology of AP. In the diagnosis of AP, serum amylase and lipase remain important tests. Advantages of amylase estimation are its technical simplicity, easy availability, and high sensitivity. However, its greatest disadvantage is its low specificity. A normal amylase would usually exclude the diagnosis of AP, with the exception of AP secondary to hyperlipidaemia, acute exacerbation of chronic pancreatitis, and when the estimation of amylase is delayed in the course of the disease. Sensitivity and specificity of amylase as a diagnostic test for AP depend on its threshold value. At a cut-off level of 1000 IU/L, it has a sensitivity of around 55 –84% and specificity up to 95%.

The major advantage of lipase is an increased sensitivity in acute alcoholic pancreatitis and in patients who initially present to the emergency room days after the onset of the disease, as lipase remains elevated longer than amylase. Although once considered to be specific for AP, nonspecific elevations of lipase have been reported in almost as many disorders as amylase, thus decreasing its specificity. Lipase assay has a sensitivity and specificity of 80% and 60%, respectively (190-191). Simultaneous estimation of amylase and lipase does not improve the accuracy. In the present study, the sensitivity, specificity, PPV, NPV of serum amylase, and serum lipase are 90%, 79.3%, 75%, 92% and 92.5%, 89.7%, 86%, and 94.5% respectively. The current study reported values are compared with Erdinc Kamer et al. and Philip Abraham et al. as shown in Table 15.

Intrapancreatic activation of trypsin is believed to play an essential part in acute pancreatitis, especially in the necrotising form of the disease. Markedly increased levels of trypsinogen-2 and trypsin-2–$\alpha_1$-antitrypsin are associated with severe disease. The increased proteolytic activity in acute pancreatitis causes the breakdown of protein and the release of peptides, which inhibit the capacity of the renal tubule to reabsorb proteins. For this reason, the concentration of trypsinogen increases much more steeply in urine than in serum. Thus, a high detection limit i.e., 50 ng per millilitre, which is more than four times the upper reference limits for urinary trypsinogen - 2) can be used for the test strip with little loss of sensitivity. The most valuable clinical feature of the dipstick test was its ability to detect all cases of severe acute pancreatitis. In the mid-1990s, urine trypsinogen concentration and TAP were reported to be of high sensitivity and specificity in diagnosing AP. Since then, determinations of urine trypsinogen concentration and TAP have been considered as good alternative biochemical tests (191,192). Result of a trypsinogen-2 dipstick test is available within 5 min, whereas TAP requires a laborious ELISA method, which takes several hours and requires skilled laboratory personnel; the rapid urinary trypsinogen-2 test does not require the use of laboratory equipment (193).

Sensitivity and specificity of UTDT in AP has been reported in the literature as 53.3%-96% and 85.7%-95%, respectively (194-201). Pezzilli et al reported a low sensitivity for UTDT in their study in which 30 patients with AP were investigated, 11 of whom were included at 2-3 d after onset of the attack. We believe that this late inclusion of a considerable number of patients in the aforementioned study might have affected urinary trypsinogen-2 concentrations and, thus might have decreased the sensitivity and specificity of UTDT for AP diagnosis. In agreement with this view, Chen et al have recently reported a gradually decreasing sensitivity for UTDT in diagnosis of AP from the first to the fourth day of admission (i.e. 90.6%, 81.2%, 59.4% and 50% on the first, second, third and fourth days of admission, respectively) (202). Considering the effect of late admission (which resulted in delayed UTDT), we did not include patients who were admitted 24 h after the onset of abdominal pain. Thus, we obtained a homogeneous study group in terms of timing of UTDT.

Also, we found sensitivity for UTDT is comparable with that for serum amylase and lipase concentrations (90% vs. 90% and 92.5%, respectively). In contrast, Hedstorm J et al. reported a higher sensitivity of UTDT compared to S. amylase and S. lipase. A urinary screening test could help reduce the risk of misdiagnosing acute pancreatitis in patients seen in the emergency department. Our results suggest such a role for the urinary trypsinogen- 2 dipstick test. A negative test result rules out acute pancreatitis with a high probability, and a positive result usually identifies patients in need of further evaluation. UTDT results interpreted in background of S. lipase provide a fairly accurate early diagnosis of AP.[12,13,14] Abdominal imaging is useful to confirm the diagnosis of AP. Abdominal ultrasound is less accurate than CT in delineating peripancreatic inflammation and detecting intrapancreatic necrosis. Abdominal USG has a low sensitivity and specificity. CECT provides over 90% sensitivity and specificity for the diagnosis of AP.

Routine use of CECT in patients with AP is unwarranted, as the diagnosis is apparent in many patients and most have a mild, uncomplicated course. However, in a patient failing to improve after 48–72 hours (e.g., Persistent Pain, Fever, Nausea, Unable to Begin Oral Feeding), CECT or MRI imaging is recommended to assess local complications such as pancreatic necrosis. Computed tomography (CT) and MRI are comparable in the early assessment of AP. MRI, by employing magnetic resonance cholangiopancreatography (MRCP), has the advantage of detecting choledocholithiasis down to 3 mm diameter and pancreatic duct disruption while providing high-quality imaging for diagnostic and/or severity purposes. MRI is helpful in patients with a contrast allergy and renal insufficiency where T2-weighted images without gadolinium contrast can diagnose pancreatic necrosis. However, MRI was not evaluated in our patients.

| Reference | On admission | Sensitivity | Specificity | PPV | NPV |
|---|---|---|---|---|---|
| Erdinc Kamer et al.(192) | Serum amylase (> 100 U/L) | 78.0 | 87.3 | 94.8 | 61.5 |
| | Serum lipase (> 60 U/L) | 86.2 | 89.4 | 96.6 | 76.0 |
| | UTDT | 91.0 | 72.0 | 96.6 | 70.4 |
| Philip Abraham et al.(193) | Serum amylase ≥3 ULN | 75.4 | 87.8 | 89.1 | 72.9 |
| | Serum lipase ≥3 ULN | 64.0 | 90.2 | 88.9 | 67.3 |
| | UTDT | 73.9 | 94.6 | 94.4 | 74.3 |
| | Ultrasonography | 74.4 | 80.0 | 82.9 | 70.6 |
| | CT scan | 84.6 | 64.3 | 81.5 | 69.2 |
| Present study | Serum amylase ≥3 ULN | 90 | 79.3 | 75.0 | 92.0 |
| | Serum lipase ≥3 ULN | 92.5 | 89.7 | 86.0 | 94.5 |
| | UTDT | 90 | 84.5 | 80.0 | 92.5 |
| | Ultrasonography | 70 | 84.5 | 75.7 | 80.3 |
| | CT scan | 94.3 | 94.8 | 91.7 | 96.5 |

***Table 15: Sensitivity, Specificity, PPV, NPV, PLR and NLR of Serum Amylase, Serum Lipase, UTDT, USG and CT in Diagnosis of AP***

In our study, age distribution was comparable among groups, males were in higher proportion compared to females. Total leucocyte count and polymorphs were significantly elevated in AP group as compared to NP group. To note, serum alkaline phosphatase and bilirubin levels are not useful in isolation in the diagnosis of acute biliary pancreatitis, although a three-fold elevation of SGPT has a positive predictive value of 96%, and SGOT is nearly as useful as SGPT according to a meta-analysis (209). If liver function enzymes and amylase and lipase levels are elevated, an aetiology of biliary pancreatitis is more likely, although pancreatic oedema causing extrinsic compression of the distal common bile duct can produce similar laboratory findings. In our study, total bilirubin, direct bilirubin, SGOT and SGPT were significantly high in AP compared to NP group. We did not find any statistical significant difference in renal parameters (S. creatinine and BUN) between the groups.

**CONCLUSIONS:** The analysis of the demographics of our study showed that 40.8% of acute upper abdominal pain were due to acute pancreatitis and 59.2% were non-pancreatic in origin. Male Patients accounted for 75.0% and 65.5% respectively in the acute pancreatitis and non-pancreatic groups. In both acute pancreatitis and non-pancreatic groups, major clustering of patients was seen in the age group of 31-40 yrs. Acute gastritis (31.0%) was the major aetiology of acute upper abdominal pain in non-pancreatic group followed by acute calculous cholecystitis (22.40%).

Alcohol (45%) was the leading cause for acute pancreatitis followed by gallstones (22.5%), idiopathic (10%) and post-ERCP (7.5%). In our study, the sensitivity of serum amylase was 90% and its specificity was 79.3% and its positive predictive value was 75% and negative predictive value was 92%. The sensitivity of serum lipase was 92.5%, its specificity was 89.7%, its positive predictive value was 86% and negative predictive value was 94.5%. Serum amylase and lipase still remain a valuable test in diagnosis of acute pancreatitis with good results. In our study, urinary trypsinogen-2 dipstick test sensitivity was 90%, specificity was 84.5%, its positive predictive value was 80.0% and negative predictive value was 92.5% which is comparable to serum amylase and serum lipase.

The advantage of urinary trypsinogen-2 dipstick test is that it is a simple bedside test with rapid reliable results which can be used on admission for early prediction of pancreatitis, thus reducing morbidity and mortality. Ultrasonography has poor sensitivity (70%) which may be contributed to bowel gas and its retroperitoneal location, hence cannot be relied upon in diagnosing acute pancreatitis, but it may help in diagnosing gallstone related pancreatitis. CT abdomen is done when there is a high degree of clinical suspicion. It has very high sensitivity (94.3%) and specificity (94.8%), Positive predictive value (91.7%) and Negative predictive value (96.5%). It is also used to assess the severity of pancreatitis.

It is clear that there is no biochemical test that can be considered to be a gold standard for the diagnosis of acute pancreatitis. Amylase and lipase remain important tests in the diagnosis of AP. Urinary Trypsinogen-2 Dipstick Test results interpreted in background of S. Lipase provide a fairly accurate early diagnosis of AP; however, larger series will validate these findings.

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