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Biochemical Evaluation of sensitivity and specificity of Severe Acute Pancreatitis.

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Abstract
Background: *Severe acute pancreatitis is one example of critical illness where both the inflammatory system & the coagulation system are to be considered as ticking bombs, where the most extreme scenarios result in multiple organ dysfunction & disseminated intravascular coagulation Microcirculatory disturbances with micro vascular thrombosis appear to play and important role both in the inflamed pancreas itself & in remote organ failure [1,2].* ***Objectives:****The aim of the study was to determine the biochemical evaluation of sensitivity and specificity of severe acute pancreatitis.* ***Methods:*** *The study was a prospective type of observational study conducted at the department of surgery, Dhaka medical college hospital, Dhaka from May 2017 to November 2017. Fifty patients above 13 years of age, admitted at general surgery unit in Dhaka medical college hospital with severe abdominal pain typically characteristics of acute pancreatitis, elevated serum amylase &/or lipase levels by at least 3- folds that of normal range were included. Meeting the inclusion and exclusion criteria a purposive sampling technique was applied for selecting the sample patients. All collected questionnaire was checked very carefully to identify the error in the data. Statistical analysis of the result was obtained by SPSS (Statistical Package for Social Sciences) version 22.* ***Results:****The specificity of amylase level is 76.9%, but the sensitivity is 94.59%. The positive predictive value 92.11 % and negative predictive value 83.3% by the cut off value 800. The serum lipase level rises 4-8 hours after the onset of symptoms, and peaks at the 24th hour of onset. The specificity of lipase level is 92.31%, but the sensitivity is 91.89%. The positive predictive value 97.14% and negative predictive value 80.0% with the cut off value 590.* ***Conclusion:*** *The findings based on biochemical predictor correlate well with the scores based on Ranson criteria during the clinical course of acute pancreatitis. This allows us to determine the severity of the disease and target the patients with high scores for close monitoring and more aggressive intervention.*

Keywords:*Severe Acute;Pancreatitis; Biochemical.*

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I. Introduction

Present study aimed to investigate plasma level of different biochemical marker in the initial phase of predicated severe AP & assess the ability of this biochemical marker to predict severe acute pancreatitis. Pancreatic necrosis usually develops within the first three days of SAP onset. Several markers are implicated in the prognostic evaluation of pancreatic necrosis. These include IL- 6, IL-8, TNF, CRP, pancreatic isoamylase, elastase. Among the markers, CRP is the only available marker in biochemical laboratories. In the diagnosis of acute pancreatitis, serum amylase & lipase remain important test. Advantage of anylase estimation is its technical simplicity, easy availability & high sensitivity. Major advantages of lipase are an increased sensitivity & remains elevated longer than amylase. At present CRP at 48 hours is the best available laboratory marker of severity. More established marker C- reactive protein has been shown to be an accurate severity predictor (sensitively& specificity above 80%) at 48 hours post-symptom onset if a cut of value of 150 mg /l is used. Acute pancreatitis (AP) is characterised by a spectrum of inflammatory disease ranging from mild to severe (6).

There are no disease-specific signs or symptoms and the diagnosis of acute pancreatitis requires a combination of clinical, laboratory, and imaging-procedure findings. A further aspect in the diagnosis of acute pancreatitis is the identification of the aetiological factors (7). Once the diagnosis has been established, the crucial aspect in the evaluation of these patients is the clinical classification according to the severity of the attack (3–5). Several biochemical markers have been described as being effective in identifyingsevere acute pancreatitis. It has been reported that serum concentrationsof C-reactive protein (CRP) (6, 7), phospholipase A2 (PLA-2) (8, 9) and non-esterified fatty acids (NEFA) increase (10), and a2 -macroglobulin decrease (11) in patients with acute pancreatitis. The aim of this study was to determine the clinical accuracy of a2 -macroglobulin, a-amylase, CRP, lipase, NEFA, pancreatic a-amylase and PLA-2 in the diagnosis and prognosis of acute pancreatitis in a group of patients with acute abdominal pain using receiver operator characteristic (ROC) curve analysis.

II. Objective

The aim of the study was to determine the biochemical evaluation of sensitivity and specificity of severe acute pancreatitis.

III. Methodology

The study was a prospective type of observational study conducted at the department of surgery, Dhaka medical college hospital, Dhaka from May 2017 to November 2017. Fifty patients above 13 years of age, admitted at general surgery unit in Dhaka medical college hospital with severe abdominal pain typically characteristics of acute pancreatitis, elevated serum amylase &/or lipase levels by at least 3- folds that of normal range were included. Meeting the inclusion and exclusion criteria a purposive sampling technique was applied for selecting the sample patients. All collected questionnaire was checked very carefully to identify the error in the data. Data processing work was consisting of registration schedules, editing computerization, preparation of dummy table, analyzing and matching of data. Statistical analysis of the result was obtained by SPSS (Statistical Package for Social Sciences) version 22.

IV. Results

Table I shows that the maximum number of patients 23(46.0%) was found in the 31-40 years of age, the next was 16(32.0%) found in 41-50 years and the lowest percentage was 11(22.0%) in the 50-60 years. The mean age of the study group was 41.86±8.27 years, minimum age 31 and maximum 58 years. Table II shows that male was 54.0% and in case of female was 46.0%. The male to female ratio was 1.2:1. Regarding co-morbid disease, maximum patients 36.0% had diabetes mellitus, 22.0% patients had diabetes and hypertension and 12.0% patients had ischemic heart disease plus diabetes.Table-3.6 showed the presenting complaints, 74% patients had H/O gallstone, 100% patients had abdominal pain, 74% patients had epigastric pain and 26.0% patients had right hypochondrium pain. Severing aching pain in 64.0% cases and burning pain 36.0%. Continuous pain 66% and 86% patient complaints pain started after taking meal and 14% patients complaints pain starts before meal. Three times increase in serum amylase level is diagnostic for acute pancreatitis. The specificity of amylase level is 76.9%, but the is positive predictive value 92.11% and negative predictive value 83.3%. The serum lipase level rises 4-8 hours after the onset of symptoms, and peaks at the 24th hour of onset. The specificity of lipase level is 92.31%, but the sensitivity is 91.89%. The positive predictive value 97.14% and negative predictive value 80.0%.

Table I: Age distribution of the patient (n=50)

AGE Distribution	n=50	%
31 years to 40 years	89	76.7
41 years to 50 years	17	14.7
51 years to 60 years	3	2.6
Mean ± SD	41.86±8.27	
Range	(31-58) years	

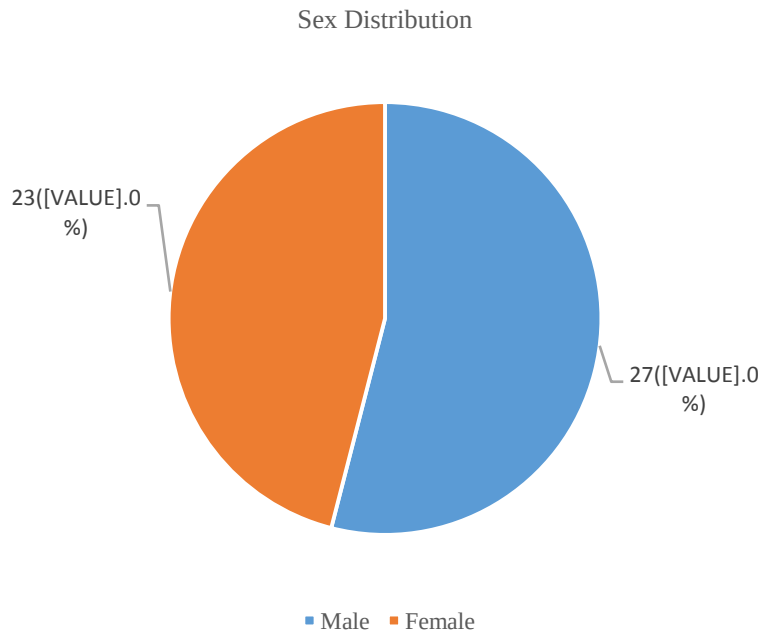

Figure I: Sex distribution of the patients (n=50)

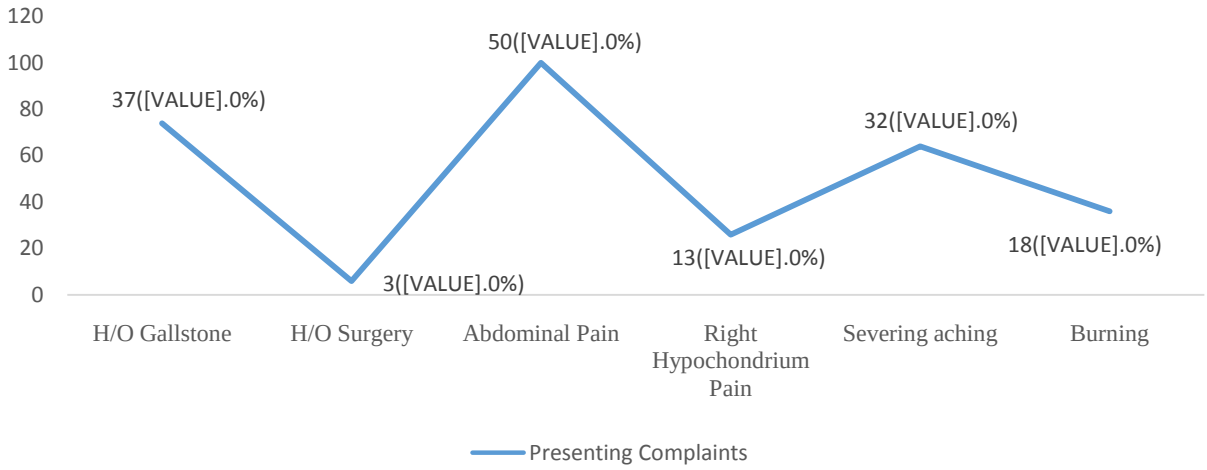

Figure II: Distribution of the study subjects by presenting complaints (n=50)

Table II: Comparison of biochemical marker and enzyme on admission and after 48-72 hrs (n=50)

Biochemical marker	On admission Mean± SD (n=50)	After 48-72 hrs Mean± SD (n=50)	P value
Serum amylase (U/L)	902.9±474.9	1058.4±489.9	<0.001*
Serum lipase (U/L)	469.7±262.4	505.2±265.9	<0.001*
Blood glucose (mmol/L)	16.86±5.86	20.24±6.70	<0.001*
Total count	18935.2±3600.1	19023.8±3611.6	<0.001*
Neutrophil	87.22±3.25	88.04±3.68	0.037*
Lymphocyte	11.97±2.31	13.05±2.92	<0.001*
ESR	97.82±10.79	100.56±12.02	<0.001*
Hb (%)	8.47±0.83	9.67±2.18	<0.001*
Serum urea (mmol/L)	18.77±5.77	21.35±7.60	<0.001*
C-reactive protein (mg/L)	166.8±13.2	169.2±21.3	0.127
Serum Billirubin (mmol/L)	3.23±1.49	2.93±0.94	0.023*
Blood urea nitrogen (mg/dl)	2.55±0.30	2.56±0.21	0.597
LDH (U/L)	467.4±16.4	736.5±107.2	<0.001*
Serum ionized calcium (mg/dl)	7.16±0.52	6.73±0.48	<0.001*

Data were expressed as mean± SD, Data were analyzed by Paired t-test, *significant, Biochemical markers and enzymes significantly increased after 48-72 hours from admission.

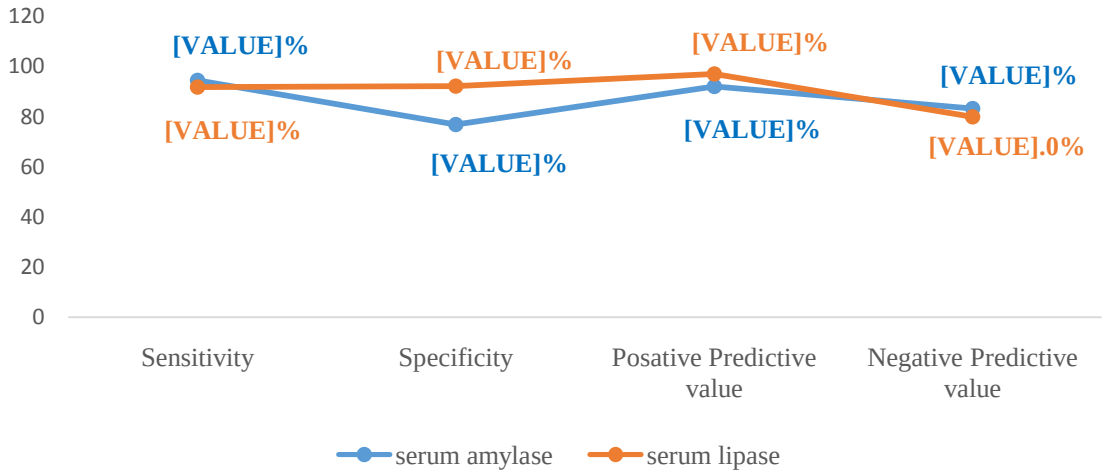

Figure III: Distribution of Diagnostic test of serum amylase and Serum lipase.

V. Discussion

Various methods have been used to predict the progress of severe acute pancreatitis, such as clinical evaluation and testing of various serological markers [13,14]. In our series, we investigated the correlation between the changes of the clinical predictors, pancreatic enzyme, the biochemical markers. In this study, we present some other aspects of the correlation among clinical, biochemical, and evaluate their prognostic value in the early assessment of severity and outcome of severe acute pancreatitis. In present study maximum 68.0% patients had severe and 32.0% had acute pancreatitis.In present study, according to the Ranson criteria, we classified 34 patients (68.0%) as having severe acute pancreatitis. We explained such high percentage of severe form of acute pancreatitis.Some study showed on the basis of Ranson criteria, they classified 44 patients (34.4%) had severe acute pancreatitis. Our results showed statistically significant higher serum concentrations of CRP in patients with severe disease. Also, changes of the CRP level during the treatment reflect the disease prognosis. Serum CRP is an acute-stage protein, i.e., synthesized in the liver. It is elevated in various inflammatory conditions, and serves as a nonspecific inflammatory marker. This parameter is usually used because it is simple and [15,16]. Also, CRP is a proven predictor of severity for acute pancreatitis when serum level of over 150 mg/L is measured within 48 hours after the onset of symptoms [17,18,19].

In our study, leukocyte count was the factor that was associated with the biochemical severity. The pancreatic enzymes derived from pancreatic acinar cells [amylase, lipase] are the cornerstone in the laboratory diagnosis of acute pancreatitis [20]. Serum lipase is a more sensitive and specific biochemical marker of acute pancreatitis than the more frequently used amylase. A raised level of serum amylase activity, at least three times the upper limit of normal, supports the diagnosis of acute pancreatitis. Its activity rises quickly within the first 12 hours after the onset of symptoms and returns to normal within three to five days. Serum amylase activities may be normal at the time of hospital admission, as a result of delayed presentation [21]. Serum amylase activities can be increased in other intra-abdominal inflammatory conditions and salivary gland pathologies, and also where there is decreased renal clearance because of renal impairment or macroamylasaemia (where amylase is bound to immunoglobulins or polysaccharides to form large molecular weight complexes[8, 17].

In this study, the specificity of amylase level is 76.9%, but the sensitivity is 94.59%. The positive predictive value 92.11% and negative predictive value 83.3% by the cut off value 800 IU/I. Some study described the sensitivity and specificity of amylase as a diagnostic test for acute pancreatitis depends on the chosen threshold value, By raising the cut off level to 1000 IUI (more than three times the upper limit of normal), amylase has a specificity approaching 95%, but a sensitivity as low as 61% in some studies (17). Compared with serum amylase, serum lipase activity remains increased for longer (up to 8 to 14 days), thereby giving greater sensitivity in patients with a delayed presentation [20]. Pancreatic lipase activities are more than four times that of amylase and as such are less likely to be affected by chronic pancreatic insufficiency. Serum Lipase level may also be raised in other intra-abdominal pathologies or in renal insufficiency. Hypertriglyceridaemia does not interfere with laboratory measurement, but drugs such as frusemide can increase lipase activity. The diagnostic accuracy of lipase appears to be better than that of amylase.

In our study, the serum lipase level rises 4-8 hours after the onset of symptoms, and peaks at the 24th hour of onset. The specificity of lipase level is 92.31%, but the sensitivity is 91.89%. The positive predictive value 97.14% and negative predictive value 80.0% with the cut off value 590 IU/I. In accordance other studied showed at a cut off activity of 600 IU/A, specificities above 95%, with sensitivities ranging between 55% and 100%. [17,22]

In conclusion, our study suggests that the results of the findings based on biochemical predictor correlate well with the scores based on Ranson criteria during the clinical course of acute pancreatitis. This allows us to determine the severity of the disease and target the patients with high scores for close monitoring and more aggressive intervention.

LIMITATIONS OF THIS STUDY

During this study, some limitations could not be overcome despite of most Sincere effort. So, it is the honest duty to admit these limitations. This study was conducted in a limited of patients which could not represent the total population effectively. Duration of study was short (six months) and single center. So, present study was not comparing other local study.

VI. Conclusion

The findings based on biochemical predictor correlate well with the scores based on Ranson criteria during the clinical course of acute pancreatitis. This allows us to determine the severity of the disease and target the patients with high scores for close monitoring and more aggressive intervention.

VII. Recommendation

Studies with larger numbers of patients, with more homogenous patient populations, and better correlation between the onset of symptoms and blood Sampling and more similarity in the assay techniques are required in order to resolve the issue.

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