## **Original Research Article**

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# Association of serum amylase and lipase levels in newly diagnosed type 2 diabetes mellitus

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#### **ABSTRACT**

Background: Type 2 diabetes mellitus is a chronic metabolic disorder due to insulin resistance caused by destruction of beta cells of pancreas. Insulin resistance in newly diagnosed type 2 diabetes mellitus patients leads to hyperglycemia. Serum amylase and lipase levels is an exocrine enzyme produced by acinar cells of pancreas. Altered levels of serum amylase and lipase leads to endocrine disorders, metabolic syndrome and diabetes mellitus.

Methods: This is a case-control study conducted in Akash Institute of Medical Sciences, A total 100 subjects (50 cases and 50 controls). All the subjects included after informed consent, blood samples are collected from the all the subjects. The serum amylase and was estimated by using enzymatic commercial available kits and fasting blood sugar (FBS), post-parandial blood sugar (PPBS), renal function test (RFT) and liver function test (LFT) was also estimated by laboratory standard methods.

Results: This study evaluated the FBS, PPBS, RFT, LFT, Amylase and Lipase levels in patients with newly diagnosed type 2 diabetes mellitus patients and compare them with healthy controls. The serum amylase and lipase levels more significantly elevated in newly diagnosed type 2 diabetes mellitus patients and compared with the healthy controls. The study also found that significantly elevated levels of FBS, PPBS, RFT and LFT in newly diagnosed type 2 diabetes mellitus patients and compared with the healthy controls, The statistically significant levels of serum amylase and lipase levels in patients with newly diagnosed type 2 diabetes mellitus when compared with the controls (p=0.0001).

**Conclusions:** The study suggesting that to estimation of serum amylase and lipase levels in newly diagnosed type 2 diabetes mellitus patients useful for early detection of diabetes mellitus and its complications. Because elevated levels of serum amylase and lipase in patients with newly diagnosed type 2 diabetes mellitus, these levels are positively correlated with the FBS and PPBS.

Keywords: T2DM, Amylase, Lipase, ADA

#### INTRODUCTION

Type 2 Diabetes mellitus (T2DM) is a chronic metabolic disorder due to dysfunction of beta cells of pancreas leads to insulin resistance caused hyperglycemia in patients with T2DM. The prevalence of diabetes mellitus estimated that 347 million individuals are effected globally in 2011, it may be raise upto double of this number till 2030, in India 72.96 million people may affect by 2030.2 This hyperglycemia leads to further micro and macro complications in T2DM patients particularly on kidney, brain, heart and retina.<sup>3</sup> In T2DM multiple pathophysiological changes occur in pancreas leads to impaired secretion of insulin along with that some signaling changes will occurs its effect on certain enzymes synthesis from the pancreas particularly amylase and lipase.4

The alpha amylase is the catalytic metalloenzyme synthesized from the acinar cells of the pancreas. It is

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involved in some physiological important functions in the body particularly on carbohydrate digestion.<sup>5</sup> The alpha amylase is the enzyme is activated by calcium, without calcium this enzyme can't work, this leads to hyperglycemia in T2DM. If any pathological changes occurs in the pancreas leads to elevated serum amylase levels are useful for diagnosing acute pancreatitis and other conditions particularly in diabetes mellitus.<sup>6</sup>

The serum lipase (Triacyl-glycerol acyl – hydrolase) is the catalytic enzyme involved in hydrolysis of ester bonds of glycerol, backbone of the lipid. This lipase is synthesized from the pancreas, any pathophysiological changes occur in the pancreas leads to elevated levels of lipase. The increased levels of serum lipase is early detective and sensitive biomarker for pancreatitis, pancreatic duct obstruction, and other pancreatic conditions particularly secondary T2DM. The secondary T2DM leads to pancreatic releated conditions, in T2DM patients elevated levels of Serum levels observed, the pathophysiological mechanism was unclear, This study was evaluated for positive correlation of serum amylase and lipase levels with FBS and PPBS and useful for further progression of newly diagnosed T2DM.

#### **METHODS**

This is a case-control study was conducted at "Akash Institute of Medical Sciences and Research Centre", Karnataka from 2017 to 2020. A total 100 subjects included in the present study 50 newly diagnosed T2DM patients was included according to American Diabetes Association Criteria (ADA) 10 and 50 age and gender matched Healthy controls also included. All the subjects were recruited in the study after obtaining their informed consent after obtaining of ethical clearance from the institute.

Patients with T2DM and age more than 30 years were included in the present study. Whoever has exclusion criteria's for both cases and controls were patients with history of hypertension, hypercholesterolemia, cardiovascular disease, hepatic disorders, acute and chronic renal insufficiency and alcohol abuse excluded from this study. From the all subjects, after overnight fasting (12 hours), 5 ml of venous blood was collected and 2 mL transferred into anticoagulant Tube contain fluoride and 3 mL transferred into plain tube. The second sample was collected for PPBS. The collected samples were separated by centrifugation at 3000 rpm for 5 min and stored until biochemical analysis was done.

Plasma fasting blood sugar (FBS), Plasma post prandial blood sugar (PPBS), serum urea, serum creatinine, serum uric acid, serum total bilirubin, serum direct bilirubin, serum aspartate transaminase (AST), serum alanine transaminase (ALT), serum alkaline phosphatase (ALP), serum gamma glutamyl transferase (GGT), serum total protein, serum albumin were measured by laboratory standard methods. Serum amylase and serum lipase was

measured by enzymatic commercial kit available in laboratory.

#### Statistical analysis

The normal distribution of data checked by using Kolmogorov Smirnov test. All the characters descriptively summarized. The mean and standard deviation about the arithmetic mean were used.

The significance difference between FBS, PPBS, RFT, LFT, amylase and lipase was analyzed by using independent student's t-test (2-tailed). The Pearson correlation was used for between the serum amylase and FBS, PPBS, RFT, LFT, Lipase and also we correlated Serum Lipase with FBS, PPBS, RFT, LFT and amylase.

The data was compiled in Microsoft excel spread sheets and analyzed using statistical package for social sciences (SPSS) for windows version 16.0. A p<0.05 was considered statistically significant.

#### **RESULTS**

Table 1 shows the mean and standard deviation (SD) values of subject's characteristics and other biochemical parameters was analysed in patients with newly diagnosed T2DM and compared with age and gender matched controls.

The positive significant difference between plasma FBS (177.26 $\pm$ 67.74, p=0.001\*), plasma PPBS (254.38 $\pm$ 83.38, p=0.001\*) and serum ALP (93.58 $\pm$ 43.19, p=0.022\*), serum GGT (44.63 $\pm$ 68.04, p=0.039\*), serum amylase (204.66 $\pm$ 44.32, p=0.001\*) and serum lipase (304.96 $\pm$ 105.95, p=0.001\*).

Elevated levels of Plasma FBS, plasma PPBS, serum ALP, serum GGT, serum amylase and serum lipase were observed in patients with newly diagnosed T2DM and compare with age and gender matched healthy controls.

Table 2 shows the correlation (pearson correlation) was done in between the serum amylase positively correlated with biochemical parameters like plasma FBS ( r=0.043, p=0.001\*), plasma PPBS (r=0.048, p=0.001\*), serum ALP (r=0.029, p=0.001\*), serum GGT ( r=0.005, p=0.001\*) and serum lipase (r=0.327, p=0.001\*) and negatively correlated with serum urea (r=0.044, p=0.665), serum creatinine (r=0.018, p=0.863), serum uric acid (r=0.069, p=0.497), serum total bilirubin (r=0.122, p=0.230), serum direct bilirubin (r=0.010, p=0.919), serum AST (r=0.058, p=0.772), serum ALT (r=0.043, p=0.961), serum total protein (r=0.165, p=0.102), serum albumin (r=0.002, p=0.982).

Table 3 shows the correlation (Pearson Correlation) was done in between the serum lipase positively correlated with biochemical parameters like plasma FBS (r=0.085, p=0.001\*), Plasma PPBS (r=0.047, p=0.001\*), serum ALP

(r=0.155, p=0.001\*), serum GGT (r=0.031, p=0.001\*) and serum amylase (r=0.327, p=0.001\*) and negatively correlated with serum urea (r=0.052, p=0.609), serum creatinine (r=0.097, p=0.338), serum uric acid (r=0.085, p=0.402), serum total bilirubin (r=0.062, p=0.540), Serum

Direct Bilirubin (r=0.158, p=0.118), serum AST (r=0.009, P p=0.933), serum ALT (r=0.019, p=0.855), serum total protein (r=0.066, p=0.517), serum albumin (r=0.062, p=0.543).

Table 1: Comparison of biochemical parameters in patients with newly diagnosed type 2 diabetes mellitus and age and gender matched healthy controls.

Parameter	T2DM Cases	Controls	P value
Age (Years)	48.54±10.87	49.82±9.93	0.540
Fasting blood sugar (mg/dl)	177.26±67.74	103.9±17.79	0.001**
Post prandial blood sugar (mg/dl)	254.38±83.38	118.86±17.13	0.001**
Serum urea (mg/dl)	21.16±12.38	20.38±6.40	0.693
Serum creatinine (mg/dl)	0.72±0.21	0.67±0.20	0.173
Serum uric Acid (mg/dl)	4.5±1.20	4.85±1.45	0.258
Serum total bilirubin (mg/dl)	0.91±0.61	0.83±0.68	0.568
Serum direct bilirubin (mg/dl)	0.36±0.39	0.28±0.19	0.220
Serum AST (IU/I)	58.06±186.70	22.36±8.60	0.180
Serum ALT (IU/I)	76.5±288.49	20.88±13.19	0.176
Serum ALP (IU/I)	93.58±43.19	77.84±20.56	0.022*
Serum GGT (IU/l)	44.63±68.04	23.6±20.61	0.039*
Serum total protein (g/dl)	7.47±0.55	7.38±0.74	0.491
Serum albumin (g/dl)	4.60±0.38	4.68±0.41	0.291
Serum amylase (IU/l)	204.66±44.32	75.6±18.65	0.001**
Serum lipase (IU/l)	304.96±105.95	75.4±25.64	0.001 **

Data expressed as Mean±SD; \* Median (Inter quartile range), \*\* more significant. TBIL: Total Bilirubin; DBIL: Direct Bilirubin; AST: Aspartate Transaminase; ALT: Alanine Transferase; ALP: Alkaline Phosphate; GGT; Gamma Glutamyl Transferase; mg/dl: Milligram per Deciliter; g/dl: Grams per deciliter; IU/l: International Units.

Table 2: Pearson correlation in between serum amylase with plasma FBS, PPBS, serum RFT and LFT and serum lipase.

Parameter		r value	P value
Serum amylase	Age	0.005	0.962
	Gender	0.052	0.609
	Fasting blood sugar (mg/dl)	0.043	0.001**
	Post prandial blood sugar (mg/dl)	0.048	0.001**
	Serum urea (mg/dl)	0.044	0.665
	Serum creatinine (mg/dl)	0.018	0.863
	Serum uric acid (mg/dl)	0.069	0.497
	Serum total bilirubin (mg/dl)	0.122	0.230
	Serum direct bilirubin (mg/dl)	0.010	0.919
	Serum AST (IU/l)	0.058	0.772
	Serum ALT (IU/I)	0.043	0.961
	Serum ALP (IU/l)	0.029	0.001**
	Serum GGT (IU/l)	0.005	0.001 **
	Serum total protein (g/dl)	0.165	0.102
	Serum albumin (g/dl)	0.002	0.982
	Serum lipase (IU/l)	0.327	0.001**

Data expressed as Mean±SD; \* Median (Inter quartile range), \*\* more significant; Rho values (r values). TBIL: Total Bilirubin; DBIL: Direct Bilirubin; AST: Aspartate Transaminase; ALT: Alanine Transferase; ALP: Alkaline Phosphate; GGT; Gamma Glutamyl Transferase; mg/dl: Milligram per Deciliter; g/dl: Grams per deciliter; IU/l: International Units.

Table 3: Pearson correlation in between serum lipase with plasma FBS, PPBS, Serum RFT and LFT and serum amylase.

Parameter		r value	P value
Serum lipase	Age	0.011	0 .911
	Gender	0 .031	0 .642
	Fasting blood sugar (mg/dl)	0 .085	0 .001**
	Post prandial blood sugar (mg/dl)	0 .047	0 .001**
	Serum urea (mg/dl)	0 .052	0 .609
	Serum creatinine (mg/dl)	0 .097	0.338
	Serum uric acid (mg/dl)	0.085	0 .402
	Serum total bilirubin (mg/dl)	0 .062	0 .540
	Serum direct bilirubin (mg/dl)	0.158	0.118
	Serum AST (IU/l)	0 .009	0 .933
	Serum ALT (IU/I)	0.019	0 .855
	Serum ALP (IU/l)	0.155	0 .027*
	Serum GGT (IU/l)	0.031	0 .062*
	Serum total protein (g/dl)	0 .066	0 .517
	Serum albumin (g/dl)	0 .062	0 .543
	Serum amylase (IU/l)	0 .327	0 .001 **

Data expressed as Mean±SD; \* Median (Inter quartile range), \*\* more significant; Rho values (r values). TBIL: Total Bilirubin; DBIL: Direct Bilirubin; AST: Aspartate Transaminase; ALT: Alanine Transferase; ALP: Alkaline Phosphate; GGT; Gamma Glutamyl Transferase; mg/dl: Milligram per Deciliter; g/dl: Grams per deciliter; IU/l: International Units.

#### **DISCUSSION**

Hyper glycaemia is caused by improper secretion and insulin resistance due to endocrine and exocrine dysfunction of beta cells of pancreas. 11 Dyslipidemia and changes of lifestyle, dietary habits are the major causes of diabetes mellitus and its complications. It causes Micro and macro vascular complications like nephropathy, neuropathy, cardiovascular, cerebrovascular and peripheral vascular complications. 12-15 The present study was analysed FBS and PPBS levels were measured in newly diagnosed T2DM patients as well as age and gender match healthy controls (p=0.001\*\*) and similar results was found in other previous studies. 16-17

The elevated levels of serum amylase and lipase were observed in newly diagnosed T2DM patients when compared to healthy controls (p=0.001). Similarly previous studys also found that the same results says that synthesis, excretion and degradation of serum amylase and lipase levels altered that given the limited pathological changes in T2DM and also they reported that several possible explanations for increased levels of serum amylase and lipase levels in newly diagnosed type 2 diabetes mellitus patients. 18-20 Some of the studys says that decreased levels of serum amylase and lipase levels are observed in T2DM patients, says that serum amylase and lipase levels are negatively correlated with the FBS, results found that the linkage of islets and acinar cells of pancreas. 21-23 Based on this conflict the present study was also supports that elevated serum amylase and lipase levels are useful for early detection and progression of newly

diagnosed T2DM patients and also the serum amylase (r=0.043 and 0.048, p=0.001\*\*) and lipase levels (r=0.085 and 0.047, p=0.001\*\*) are positively correlated with the fasting blood sugar and post prandial blood sugar.

The present study was also measured serum RFT and serum LFT in newly diagnosed T2DM patients and compare with age and gender matched healthy controls. There is a significance difference between serum alkaline phosphatase and serum gamma Glutamyl Transferase levels in newly diagnosed T2DM patients when compared to healthy controls and also no significance difference between serum RFT and serum total bilirubin, serum direct bilirubin, serum aspartate transaminase, serum alanine transaminase, serum total proteins and serum albumin levels.

The increased serum amylase and serum lipase activity in diabetes and prediabetes groups can interfere the exocrine and endocrine interactions because insulin. The high activity of lipase and amylase in diabetes and prediabetes groups are associated with an impaired insulin action due to insulin resistance and inadequate insulin secretion leads to hyperglycemia in newly diagnosed T2DM patients. <sup>24-25</sup> These studies suggest that to measure serum amylase ad serum lipase levels useful early detection of T2DM patients and further progression.

### Limitations

This study didn't followed up and also less sample size, large sample size and follow up studies are required.

#### **CONCLUSION**

In conclusion the study suggesting that the estimation of serum amylase and lipase levels in newly diagnosed type 2 diabetes mellitus patients useful for early detection of diabetes mellitus and its complications. Because elevated levels of serum amylase and lipase in patients with newly diagnosed type 2 diabetes mellitus, these levels are positively correlated with the FBS and PPBS.

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Institutional Ethics Committee

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