

## Original Research Article

# The assessment of serum amylase in patients with type-II diabetes mellitus

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### ABSTRACT

**Background:** Diabetes mellitus (DM) is a metabolic disorder that causes excessively high blood glucose levels. As there is an interrelationship between the functional and anatomical portions of the pancreas, it may affect the exocrine portion as well. Aim of the study was to assess the level of serum amylase and random blood glucose in patients with T2DM compare and correlate it with healthy controls.

**Methods:** This Analytical cross sectional study was conducted in the Parul Sevashram, Hospital, Vadodara. We enrolled 100 type 2 diabetic subjects aged 40 to 60 years and 100 healthy patients to analyze their blood glucose and serum amylase levels.

**Results:** We found statistically sig ( $P < 0.01$ ) lower serum amylase levels in T2DM patients compared to healthy controls. Cases had significantly higher RBS levels than controls. The mean $\pm$ SD of RBS of group-1 was 142.29 $\pm$ 62.296 mg/dl, group-2 was 105.36 $\pm$ 23.336 mg/dl. The mean $\pm$ SD of serum amylase of group-1 was 65.949 $\pm$ 29.5554 u/l, group-2 was 87.82 $\pm$ 42.4896 u/l. In our study we found weak negative correlation between Plasma blood glucose and serum amylase in cases, having statistical sig  $P$  value= 0.0001 and  $r$  value was -0.384.

**Conclusions:** The results of our study shown that in T2DM cases, where the RBS level was higher; the serum amylase activity was significantly lower. This represented a malfunction in the pancreas endocrine-exocrine axis, as any pathological change that impacted any section of an organ would affect the surrounding area of that organ functionally.

**Keywords:** Exocrine pancreas, Serum amylase, Type II diabetes mellitus

### INTRODUCTION

Diabetes is a chronic disease caused by insufficient insulin production by the pancreas or inadequate absorption of insulin by the body. Insulin-like hormone controls blood sugar levels.<sup>1</sup> Long-term harm, dysfunction, and failure of numerous organs, particularly the eyes, kidneys, nerves, heart, and blood vessels, are linked to the chronic hyperglycemia of diabetes.<sup>2</sup>

Diabetes mellitus diagnostic criteria according to WHO

guidelines are as follows: fasting plasma /serum glucose <126 mg/dl, 2-hour postprandial glucose <200 mg/dl, random plasma glucose <200 mg/dl.<sup>3</sup> The most prevalent endocrine condition is DM, Which is expected to affect more than 300 million population globally in the year 2025.<sup>4</sup> At the moment, diabetes mellitus is most prevalent in India.<sup>5</sup> Diabetes mellitus is a heterogeneous group of multifactorial, polygenic syndromes, not a single illness, with high fasting blood glucose (FBG) brought on by a relative or absolute insulin shortage.<sup>6</sup> Diabetes can cause hypoglycemia and ketoacidosis as its

short-term consequences. The long-term consequences include diabetic retinopathy, nephropathy and neuropathy. Cardiovascular illness is connected to diabetic macroangiopathy. Diabetes deaths are currently most commonly caused by cardiovascular disease.<sup>7</sup> Pancreas performs an important function in transforming the food we eat into energy for the body's cells. The pancreas serves two primary purposes: an endocrine activity that controls blood sugar and an exocrine function, i.e. digesting enzymes are released through the entire pancreatic duct.<sup>8</sup>

In both animal and humans with type 2 diabetes mellitus, the continuous interstitial matrix connection between the endocrine and exocrine pancreas is disrupted, leading to a disordered insulino-acinar-ductal-cretin gut hormonal axis. The synthesis and release of enzymes in the exocrine pancreas may be impacted by a number of problems in type 2 diabetes' insulin secretion and signalling, in addition to these proposed processes. Moreover, the autonomic nervous system and the hormones cholecystokinin and secretin, which are found naturally in the gut, regulate the pancreatic juice's secretion.<sup>9</sup>

Amylase is an exocrine enzyme produced by pancreatic acinar cells that has been associated to endocrine diseases such as metabolic syndrome and diabetes. We hypothesised that low blood amylase levels may be connected to decreased islet cell function in type 2 diabetes.

Aim of this study was to check the RBS and serum amylase levels and correlate serum amylase levels with random blood glucose in type-II DM patients and healthy controls.

**METHODS**

This was an analytical cross sectional study carried out in Parul Sevashram Hospital affiliated to Parul University, Vadodara from October 2022 to March 2023. Approval of institutes Scientific Review Committee Institutional Ethics Committee for Human Research (PU-IECHR) was obtained. 100 type II diabetic subjects aged 40 to 60 years of both sexes were enrolled in this study from Medicine OPD of Parul Sevashram Hospital, Vadodara, also 100 healthy volunteers were enrolled as control group.

The inclusion criteria for cases and controls were as follows: Patients having type-II DM since past 1 year and having age between 40-60 years and for Controls: Patients relatives and our laboratory staff were taken as age and sex matched healthy controls. While patients suffering from acute and chronic pancreatitis, pregnant women, and newly diagnosed type-II diabetic patients were excluded out from our study. Informed consent of subjects was obtained for participation in the study and for blood collection. Venous blood sample was collected

in plain vacutainer for estimation of serum amylase and in fluoride vacutainer for estimation of plasma blood glucose. Plasma blood glucose was estimated by GOD-POD method on fully automated biochemistry analyzer, while serum amylase was estimated by CNPG3 kinetic method on semi-automated analyzer.

**Statistical analysis**

The data was statistically analysed using the independent T-test to find out the significance difference between the groups. Pearson's correlation coefficient (r value) was used to find out correlation between parameters of the study group. All the data were expressed in terms of Mean±SD. p value <0.05 was considered as statistically significant All Statistical analysis was done using SPSS Statistics 26 Software.

**RESULTS**

In our study we divided our subjects into two groups as follows: where group-1 consists of cases and group-2 consists of healthy controls. Table 1 group-1 (cases) and group-2 (controls) shows the physical characteristics and lab parameters of the research individuals. The mean ages of the two groups were comparable, with the diabetes patients group being 51.53±6.111 years old and the healthy control group being 51.01±7.222 years old. In group I, there were 37% males and 13% females, compared to 38% males and 12% females in group II. RBS was significantly higher in type II diabetics (142.29±62.296) as compared to healthy persons (105.36±23.336). The mean serum amylase activity in the case group was 65.946±29.555 u/l and 87.82±42.489 u/l in the control group.

**Table 1: Physical characteristics and laboratory parameters of study groups.**

Variables	Group 1 (n = 100) Mean±SD	Group 2 (n = 100) Mean±SD	P value
Age (years)	51.53±6.111	51.01±7.222	0.583
Male	73 (37%)	75 (38%)	-
Female	27 (13%)	25 (12%)	-
RBS (Mg/dl)	142.29±62.296	105.36±23.336	<0.01*
Serum amylase (IU/L)	65.949±29.5554	87.82±42.4896	0.001*

\*(significant)

Figure 1 shows the percentage of males and females in our study. Table 2 shows the weak negative correlation between serum amylase activity and blood glucose in diabetes patients. It shows that as there is increase in blood glucose levels in patients with type 2 diabetes there is significant decrease in serum amylase levels (p=0.001).

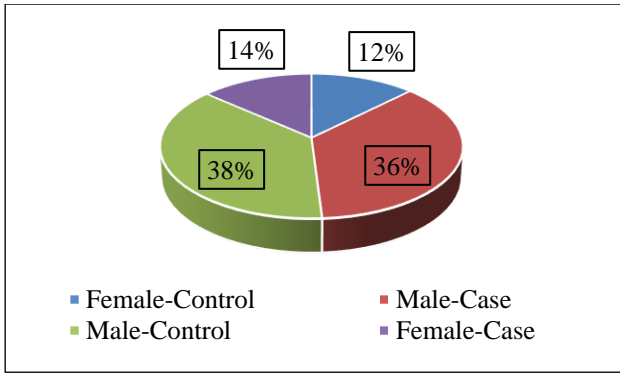


Figure 1: Sex distribution in our study groups.

Table 2: Correlation of serum amylase with RBS in cases.

Parameter	Coefficient of correlation (r)	95% confidence interval	P value
RBS (Mg/dl)	-0.3844	-0.5400 to -0.2033	0.0001**

\*\*(Highly significant)

Figure 2 shows that Weak negative correlation between plasma blood glucose and serum amylase in cases, having statistical sig p value= 0.0001 and r value was -0.384 with 95% confidence interval of -0.5400 to -0.2033.

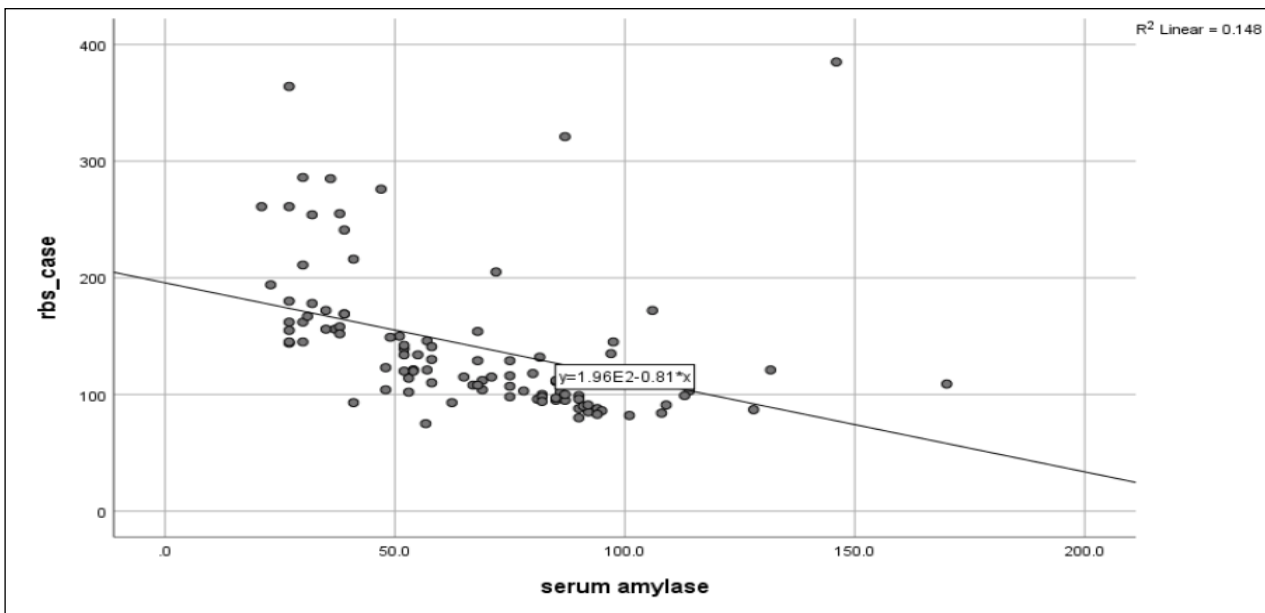


Figure 2: Correlation of serum amylase with RBS in cases.

## DISCUSSION

Insulin resistance in diabetic individuals causes exocrine acinar cells to atrophy and anti-insulin hormone activity to rise. As a result, there is a reduction in exocrine pancreatic enzyme production and secretion. In our investigation; there was a statistically significant negative connection between serum amylase and the length of diabetes. The relationship between serum amylase and duration of diabetes was statistically significant, and amylase in type 2 diabetic subjects experienced more severe effects in cases of diabetes mellitus that had been present for a long time. These findings suggest that measuring serum amylase levels in diabetics may be useful for determining how diabetes develops.

In our study, 200 participants with type 2 diabetes who had been diagnosed a year before were included. Of those, 100 were allotted to the case group as having type 2 diabetes mellitus, and 100 were allotted to the control group as not suffering from the disease.

In the present study, subjects with type 2 diabetes mellitus had a mean±SD age of 51.53±6.111 years, whereas controls had a mean ± SD age of 51.01±7.222 years, indicating a not significant difference with p=0.583. Yadav et al and Subedi et al results were similar to our findings.<sup>10,11</sup>

In our study, out of 100 participants in the case group, 73% were male and 27% were female. Out of 100 participants in the control group, 75% were male and 25% were female. In many additional researches, the case and control group's sex distribution were as follows; Munta et al in their study out of cases group 62% were male and 38% were female and in control group 51.1% male and 48.8% female, Mishra et al in their study out of cases group 57.8% were male and 42.2% were female and in control group 71.4% were male and 35.7% were female, in Noor-E-Jannat et al in their study out of cases group 44% were male and 56% were female and in control group 48% were male and 52% were female, Kumar et al in their study out of cases group cases 58%

were male and 42% were female and in control group 58% were male and 42% were female.<sup>12-15</sup>

We did comparison of random blood sugar between case (group-I) mean±SD (142.29±62.296) and control (group-II) mean±S.D (105.36±23.336) with a p value of <0.01. In contrast to our study no study did mean±SD of random blood glucose between cases and controls. Following studies done by Hareesh et al (2021).<sup>16</sup> They have compared FBS in cases and control group with significant p-value (p= <0.001).

We compared the serum amylase levels between the cases (group-I) mean and standard deviation (65.949±29.555) and the control (group-II) mean and standard deviation (87.82±42.489), with a p value of 0.001 being considered statistically significant and this p-value was in agreement with, Basavaraj et al, and Kalital et al.<sup>17,18</sup> However in contrast to our findings, Jain et al did not find any significant difference in serum amylase levels between cases and control groups.<sup>19</sup>

This means that people with type II diabetes have considerably lower blood amylase levels than non-diabetic patients, suggesting that diabetes has a statistically significant p value 0.001; our study demonstrated that the case group serum amylase levels were lower than those of control group.

We did correlation between random blood sugar and serum amylase in group-I cases. We found in our study significantly weak negative correlation between random blood sugar levels and serum amylase levels in group-I cases (r= -0.3844, p value =0.0001).

The present study has few limitations. This study represents only a drop in the ocean of diabetes research, and larger samples are needed to identify more statistically meaningful data and potential. This investigation can undoubtedly yield new results and opportunities. A longer research period is required with regular follow up samples to check the effect of long term diabetes on pancreatic functions.

## CONCLUSION

The results of our study shown that in type 2 diabetes mellitus, where the blood glucose level was higher; the serum amylase activity was significantly lower. This represented a malfunction in the pancreas endocrine-exocrine axis, as any pathological change that impacted any section of an organ would affect the surrounding area of that organ functionally.

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*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Parul University's Institutional Ethics Committee on Human Research (PU-IECHR)*

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