Research Article

CLINICAL INVESTIGATION

# Awareness About Routine Laboratory Investigations Amongst Type 2 Diabetes Mellitus Patients and its Impact on Their Disease Status


## Abstract

**Introduction:** Routine laboratory biochemical blood investigations are an integral part of therapeutic intervention and early diagnosis and prevention of Diabetic complications.

This study was undertaken to assess the level of awareness amongst already diagnosed Diabetes mellitus patients regarding the laboratory investigations, their importance, time interval, and relevance to the disease process through a validated questionnaire form.

**Materials and Methods:** The enrolled Type 2 Diabetes mellitus patients in the age group 30-80 years of both sexes were given a validated self-administered study questionnaire consisting of 10 questions related to various routine laboratory tests required to be done at specified time intervals for better management and prevention of complications. The awareness level was analyzed by scores assigned to each response as correct, wrong, or don't know as 2, 1, and 0.

Laboratory investigations done were FBS, PPBS, Lipid profile, Urea, Creatinine, Total protein, and Albumin.

The scores of questionnaires were correlated with the laboratory results reflecting the disease status.

**Results:** There was a gross lack of awareness about the laboratory investigations to be done for proper monitoring of the glycemic status. Participants with higher Overall scores, Monitoring scores, and Morbidity scores had their blood sugar levels in the normal range compared to participants with lower scores.

**Conclusion:** This observation emphasized the need for proper education to the patients regarding self and timely monitoring of blood parameters related to the disease process as well as routine check-ups with the physicians in the prevention of metabolic derangements.


**Keywords: Diabetes mellitus, Awareness, Questionnaire, Monitoring score, Morbidity score, Diabetic Health Literacy**

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## Introduction

Diabetes mellitus is slowly becoming a national epidemic among NCDs (Non-Communicable Diseases). It is a growing challenge in India with an estimated 8.7% diabetic population in the age group of 20 and 70 years [1]. The number of people with diabetes in India currently, which is around 77 million, is expected to rise to 134 million by the next 25 years as per projections by the ninth edition of the International Diabetes Foundation Diabetes Atlas [2]. Diabetes management is multipart and multi-faceted. The majority of patients find it difficult and lack the expertise and knowledge to handle the level of self-care expected to attain the indorsed goals for adequate control of the disease [3]. Lack of adequate diabetes health literacy has been independently associated with failing glycemic control and higher rates of microvascular and macrovascular complications associated with Diabetes mellitus such as cardiovascular diseases, neuropathy, retinopathy, and nephropathy [4]. As knowledge about the disease

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influences decisions about diet, exercise, weight control, blood glucose monitoring, medication use, and prevention and treatment of microvascular and macrovascular complications, many national and international agencies including the American Diabetes Association have promoted patient education programs for diabetes [5, 6]. Educational intercessions for diabetes have unwaveringly shown to improve patients' knowledge about self-care activities required, quality of life, timely checking and monitoring of fasting glucose, HbA1c level, cholesterol, urinary protein/microalbumin, blood pressure, and weight. [7-9]. Variables found to be associated with poor diabetes health literacy included educational level, socioeconomic status, duration of disease, age, and gender as documented in various studies [10-14].

Routine laboratory biochemical blood investigations are an integral part of therapeutic intervention and early diagnosis and prevention of Diabetic complications. Blood tests comprising of fasting and postprandial blood sugar (FBS/PPBS), Glycated Hemoglobin(HbA1c), Lipid profile (Cholesterol, Triglycerides, HDLc, LDLc, and VLDL), Urea, Creatinine, Total protein, Albumin, and urine Microalbumin along with blood pressure, retinal, foot and nerve examination should be routinely done at specified time intervals to assess the efficacy of therapy, glycemic control, and early detection of complications like cardiovascular diseases, nephropathy, retinopathy and neuropathy [15,16].

Therefore, awareness amongst the patients regarding routine laboratory investigations in the specified time interval is very essential for better disease management and prevention /early diagnosis of complications. However, data relating the association between Diabetes status with timely laboratory testing is scarce.

Hence, this study was undertaken to assess the level of awareness amongst already diagnosed Diabetes mellitus patients regarding the laboratory investigations, their importance, time interval and relevance to the disease process through a validated questionnaire form. The awareness level was also assessed taking into account the demographic profile and duration of the disease. The correlation was analyzed with biochemical parameters like FBS, Lipid profile, HbA1c, Urea, Creatinine, Total protein, and Albumin.

## Materials and Methods

This Cross-sectional study was conducted from November 2018-June to 2019. 300 diagnosed Type 2 Diabetes mellitus patients in the age group 30 years-80 years of both sexes with a duration of disease more than 5 years were included in the study after obtaining informed written consent. Ethical approval was obtained from the Institute Ethics Committee.

The enrolled cases were given a self-administered study questionnaire form consisting of 10 questions related to awareness regarding various routine laboratory tests required to be done at specified time intervals and long-term complications associated with Diabetes mellitus in case of deranged metabolic status (Table 1).

The questionnaire was in English and the local vernacular language of the state. The awareness level

**Table 1: Self-administered Study Questionnaire Form**

| Q. No. | Question asked | Response Option a | Response Option b | Response Option c |
|---|---|---|---|---|
| 1 | Do you routinely check your blood sugar levels? | Yes | No | At convenience |
| 2 | In what intervals FBS and PPBS should be checked after the detection of Diabetes? | Monthly once | Once in three months | Yearly once |
| 3 | How many hours of fasting should be done before coming for a blood examination in Diabetes patients? | 6 hours | 8 hours | 12 hours |
| 4 | Do you know about SMBG (Self-Monitoring of Blood Glucose)? | Yes | No | Not exactly |
| 5 | Do you know prolonged poorly controlled Diabetes can affect vision? | Yes | No | Not exactly |
| 6 | Do you know prolonged poorly controlled Diabetes can affect kidneys? | Yes | No | Not exactly |
| 7 | Do you know prolonged poorly controlled Diabetes can affect nerves? | Yes | No | Not exactly |
| 8 | Do you know prolonged poorly controlled Diabetes can affect heart and blood vessels? | Yes | No | Not exactly |
| 9 | Do you know about the harmful effects of Diabetes on Cholesterol and other lipids? | Yes | No | Not exactly |
| 10 | Have you ever checked for the presence of protein /albumin (MICRAL test) in urine after the detection of Diabetes? | Yes | No | Do not remember |

was analyzed by scores assigned to each response as correct, wrong, or don't know as 2, 1, and 0. The scores obtained were divided into two groups for analysis: The monitoring score which comprised the scores obtained about laboratory investigations and the Morbidity score included those for micro and macrovascular complications associated with the disease process.

Blood samples were then collected from each participant and the following tests were carried out Fasting Blood Sugar (FBS), Lipid profile, Urea, Creatinine, Total protein, and Albumin.

The scores of questionnaires were correlated with the laboratory results reflecting the disease status.

Descriptive statistics using standard statistical software was used for the purpose. The demographic and biochemical profile of the study population was expressed in Mean ± SD. Diabetic Patients' Awareness to various parameters was calculated in percentage Kendall's tau-b correlation test of various awareness parameters to deranged blood sugar levels in patients was done. The odds ratio was calculated with significance analyzed by Chi-Square test. Independent sample t-test was done to assess the difference in awareness score based on gender and participants with normal vs deranged blood sugar levels. $p<0.05$ was considered statistically significant.

## Observations

In our study population of 300 participants, there were 199 males and 101 females with the average age being 53.7 years ± 10.9 years. Duration of Diabetes was found to be 6.6 years ± 5.9 years. Apart from FBS and HbA1, all other biochemical parameters had an average value within the normal range in the study population (Table 2).

The study population's awareness of various parameters enumerated in the questionnaire is depicted in Table 2. It was observed that patients were aware of long-term complications associated with Diabetes mellitus. More than 50% of the study population were found to be aware that prolonged Diabetes mellitus affects the eye, (retinopathy) kidneys (nephropathy), nerves(neuropathy), and heart (Cardiovascular complications) and also leads to derangement of lipid profile. But it was very evident from the study that there was a gross lack of awareness about the laboratory investigations to be done for proper monitoring of the glycemic status. Proper intervals for checking blood sugar level was known to only 36% of the study participants whereas only 19% of the study population had proper knowledge regarding hours of fasting before blood examination. This is of concern as improper preparations and inappropriate duration of fasting may lead to erroneous laboratory results affecting proper management and monitoring of the disease process. 42% of the study population had information about SMBG. Test for proteinuria or microalbuminuria (MICRAL test) was not known to more than 58% of the study participants which is quite alarming looking at the rising trend of Diabetic nephropathy in India (Table 3).

From the calculated scores, it was observed that the overall score as well as both Monitoring and Morbidity scores were higher amongst the male participants compared to female participants and the difference was statistically significant with a p-value <0.05. Age had no significant correlation to any of the awareness scores as measured by linear regression nor any significant correlation by Pearson's Correlation. The gender-based difference in the scores may be attributed to socioeconomic parameters like education and the tendency of the female population to neglect their health conditions which is a common problem in India (Table 4).

## A. Independent Sample's t-test

Age had no significant correlation to any awareness score as measured by linear regression nor any significant correlation by Pearson's Correlation.

The correlation between awareness about the laboratory investigations and long-term complications associated with Diabetes mellitus with normal and deranged blood sugar values in the study participants was analyzed by Kendall's tau b correlation. The Odds Ratio was calculated and

**Table 2: Demographic and Biochemical Profile of the Study Population.**

| Parameters | Mean ± SD |
|---|---|
| Sex: Male, Female | 199 (66.3) |
| | 101 (33.7) |
| Age (in years) | 53.7 ± 10.9 |
| Duration of Diabetes (in years) | 6.6 ± 5.9 |
| Creatinine (in mg/dL) | 1 ± 0.3 |
| Total Cholesterol (in mg/dL) | 184.5 ± 46.6 |
| Triglycerides (in mg/dL) | 148.4 ± 89.9 |
| HDL (in mg/dL) | 48 ± 14.7 |
| VLDL (in mg/dL) | 30.9 ± 18.1 |
| LDL (in mg/dL) | 108.3 ± 34.1 |
| FBS (in mg/dL) | 147.5 ± 54.3 |
| HbA1c | 8 ± 2.8 |

| Table 3: Diabetic Patients' Awareness of various parameters | | | |
|---|---|---|---|
| **Awareness To** | | **n [N=300]** | **%** |
| Routinely check blood sugar levels | Yes | 152 | 51% |
| | No | 70 | 23% |
| | Somewhat or Maybe | 78 | 26% |
| Check FBS or PPBS in proper intervals | Yes | 108 | 36% |
| | No | 122 | 41% |
| | Somewhat or Maybe | 70 | 23% |
| Proper knowledge regarding hours of fasting before blood examination | Yes | 58 | 19% |
| | No | 137 | 46% |
| | Somewhat or Maybe | 105 | 35% |
| Aware about SMBG | Yes | 125 | 42% |
| | No | 139 | 46% |
| | Somewhat or Maybe | 36 | 12% |
| Aware that prolonged T2DM can affect vision | Yes | 157 | 52% |
| | No | 121 | 40% |
| | Somewhat or Maybe | 22 | 8% |
| Aware that prolonged T2DM can affect kidneys | Yes | 166 | 55% |
| | No | 97 | 32% |
| | Somewhat or Maybe | 37 | 13% |
| Aware that prolonged T2DM can affect Nervous System | Yes | 165 | 55% |
| | No | 104 | 35% |
| | Somewhat or Maybe | 31 | 10% |
| Aware that prolonged T2DM can affect Cardiovascular system | Yes | 173 | 58% |
| | No | 103 | 34% |
| | Somewhat or Maybe | 24 | 8% |
| Aware that prolonged T2DM can affect Lipid Profile | Yes | 158 | 53% |
| | No | 99 | 33% |
| | Somewhat or Maybe | 43 | 14% |
| Aware about testing for Protein in Urine after detection of T2DM | Yes | 73 | 24% |
| | No | 173 | 58% |
| | Somewhat or Maybe | 54 | 18% |

| Table 4: Difference in Awareness Score based on Sex | | | |
|---|---|---|---|
| **Awareness Score** | **Male (n=199)** | **Female (n=101)** | **p-value [a]** |
| Overall Score | 11.16 ++ 4.80 | 9.39 ++ 4.92 | 0.003 |
| Monitoring Score | 4.86 ++ 2.11 | 4.03 ++ 2.41 | 0.002 |
| Morbidity Score | 6.29 ++ 3.40 | 5.37 ++ 3.32 | 0.024 |

$p<0.05$ was taken as statistically significant assessed by the Chi-square test (Table 5). The awareness evaluated with the deranged glycaemic status of the patients indicates the effect of lack of proper and timely monitoring by laboratory investigations on the metabolic profile and risk of long-term micro and macrovascular complications associated with Diabetes mellitus. Amongst the study participants, the patients with decreased awareness levels regarding routine check-ups of blood sugar levels had deranged blood sugar levels with a positive correlation of 0.193 and an Odds Ratio of 2.634 which was statistically significant ($p<0.001$) (Table 5). Participants with decreased awareness levels about micro and macrovascular complications like nephropathy, neuropathy, cardiovascular diseases, and deranged lipid profile associated with Diabetes mellitus had deranged blood sugar values with a positive correlation and Odds Ratio, both being statistically significant ($p<0.01$) (Table 5).

### B. Aware includes patients who opted for both Yes and Somewhat/Maybe

a. Kendall's tau-b

b. Chi-Square test

The awareness score was analyzed in three categories as Overall score, Monitoring score, and Morbidity scores determined from their responses to the questionnaire and knowledge about the laboratory investigations to be done, and associated micro and macro vascular complications with Diabetes mellitus. It was very clearly evident that participants with higher Overall scores, Monitoring scores, and Morbidity scores had their blood sugar levels in the normal range compared to participants with lower

| Table 5: Correlation and Odds Ratio of various Awareness Parameters to Deranged Sugar Levels in Patients | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Awareness Parameter#** | | **Blood Sugar Levels** | | | | **Correlation [a]** | **Odds Ratio** | **p-value [b]** |
| | | **Normal** | | **Deranged** | | | | |
| | | **n [N= 138]** | **%** | **n [N = 162]** | **%** | | | |
| Routinely check blood sugar levels | Aware | 118 | 85.51 | 112 | 69.14 | **0.193** | **2.634** | **0.001** |
| | Not Aware | 20 | 14.49 | 50 | 30.86 | | | |
| Check FBS or PPBS in proper intervals | Aware | 89 | 64.49 | 89 | 54.94 | 0.097 | 1.49 | 0.093 |
| | Not Aware | 49 | 35.51 | 73 | 45.06 | | | |
| Proper knowledge regarding hours of fasting before blood examination | Aware | 78 | 56.52 | 85 | 52.47 | 0.041 | 1.178 | 0.482 |
| | Not Aware | 60 | 43.48 | 77 | 47.53 | | | |
| Aware about SMBG | Aware | 74 | 53.62 | 87 | 53.7 | -0.001 | 0.997 | 0.989 |
| | Not Aware | 64 | 46.38 | 75 | 46.3 | | | |
| Aware that prolonged T2DM can affect vision | Aware | 88 | 63.77 | 91 | 56.17 | 0.077 | 1.373 | 0.181 |
| | Not Aware | 50 | 36.23 | 71 | 43.83 | | | |
| Aware that prolonged T2DM can affect kidneys | Aware | 106 | 76.81 | 97 | 59.88 | 0.18 | 2.22 | 0.002 |
| | Not Aware | 32 | 23.19 | 65 | 40.12 | | | |
| Aware that prolonged T2DM can affect Nervous System | Aware | 106 | 76.81 | 90 | 55.56 | 0.223 | 2.65 | <0.001 |
| | Not Aware | 32 | 23.19 | 72 | 44.44 | | | |
| Aware that prolonged T2DM can affect Cardiovascular system | Aware | 114 | 82.61 | 83 | 51.23 | 0.329 | 4.521 | <0.001 |
| | Not Aware | 24 | 17.39 | 79 | 48.77 | | | |
| Aware that prolonged T2DM can affect Lipid Profile | Aware | 105 | 76.09 | 96 | 59.26 | 0.178 | 2.188 | 0.002 |
| | Not Aware | 33 | 23.91 | 66 | 40.74 | | | |
| Aware about testing for Protein in Urine after detection of T2DM | Aware | 64 | 46.38 | 63 | 38.89 | 0.076 | 1.359 | 0.191 |

| Table 6: Difference in Awareness Score in Patients with Normal vs Deranged Blood Sugar Levels | | | |
|---|---|---|---|
| | **Blood Sugar Levels** | | |
| | **Normal** | **Deranged** | **p-value [a]** |
| Overall Score | 12.24 ± 4.81 | 9.14 ± 4.53 | **<0.001** |
| Monitoring Score | 5.05 ± 2.46 | 4.18 ± 1.97 | **0.001** |
| Morbidity Score | 7.18 ± 2.94 | 4.96 ± 3.44 | **<0.001** |

scores and it was statistically significant with p<0.001. This observation very aptly emphasizes the need for proper education to the patients regarding self and timely monitoring of blood parameters related to the disease process as well as routine checkups with the physicians in the prevention of metabolic derangements and long-term complications associated with Diabetes mellitus which is the major cause of morbidities and mortalities associated with the disease process (Table 6).

### C. Independent Sample's t-test

Figure 1 shows the percentage of awareness of parameters related to laboratory investigations and complications associated with the disease process in long run to blood sugar values of the patients. From the observations, it was evident that people with higher awareness levels had blood sugar levels in the normal range compared to participants with a lower degree of awareness of routine and timely assessment of laboratory investigations and knowledge about long-term complications associated with metabolic derangements associated with the disease process.

## Discussion

Diabetes Mellitus is gradually becoming a global pandemic amongst non-communicable diseases worldwide. In India, the rise is alarming .so also associated with microvascular and macrovascular comorbidities. The management of this disease is multi-faceted because of its multifactorial pathophysiology. In this context, the role of physicians as well as the patient himself/herself is very crucial. Self-monitoring of glycemic status, and routinely and timely laboratory investigations reflect the metabolic status of the body and the long-term complications affecting various organs with micro and macrovascular complications like retinopathy, neuropathy, nephropathy, and cardiovascular diseases. Hence, it is highly essential for timely intervention and prevention of complications. For this, Diabetes awareness education is the need of the time and has been advocated by all major bodies associated with the management of Diabetes and the prevention of complications thereby reducing morbidities and mortalities associated with this multifactorial metabolic disorder.

In our study, the study population had a deranged glycemic control and awareness about periodic checkups of blood sugar, HbA1c, and even the duration of fasting to be done before testing was inadequate (Table 2, Table 3). Our study

corroborates with the observations of Fenwick et al who documented that worse glycemic control was independently associated with worse diabetes knowledge [17]. We found that patients with an average duration of Diabetes mellitus of 6.6 years ± 5.9 years Table 2 were not aware of checking urine protein though they had the knowledge that prolonged duration of Diabetes mellitus can affect kidneys, eyes, nervous system, and cardiovascular system. Hence, there was a clear discrepancy in knowledge regarding the disease and self-care activities related to the control of the disease with the prevention of comorbidities (Table 3). Despite the high level of awareness about complications associated with prolonged Diabetes mellitus, the level of patients' compliance with behaviors to reduce the risk was low. Bakkar et al in their study on awareness about diabetic retinopathy among patients with Diabetes mellitus too documented similar observations in their study population in Jordan [18].

From Table 3 it was evident that patients had limited knowledge about the timing of laboratory investigations like fasting blood sugar, duration of fasting, and detection of protein in the urine. This was further corroborated by deranged glycemic status in participants who were not aware of routine checkups of blood sugar values and this was statistically significant as revealed by Table 5 in our study. Interestingly, participants were aware of micro and macrovascular comorbidities associated with prolonged Diabetes mellitus (Table 3) and the awareness was also reflected in their glycemic status with a statistically significant derangement in the group not aware of these comorbidities compared with a group who were aware of documented in Table 4. This reinforces the need for proper Diabetic health literacy for optimal diabetes control goals and related self-care activities [5,6,19].

Our study depicted a positive correlation between awareness about laboratory investigations and comorbidities with derangement in glycemic status. For people who were more aware, a greater percentage of them had their sugar levels and HbA1c within normal limits whereas, amongst participants with limited knowledge, the majority had deranged blood sugar levels (Figure 1). Our study is a pilot study on the correlation between awareness level and laboratory parameters. But similar studies on awareness between Diabetes retinopathy (DR) and the occurrence of DR have shown that proper knowledge about DR has led to adequate self-care activities and a reduction in DR incidences amongst Diabetes mellitus patients [20,21].

Many studies have documented that patients with proper Diabetic health literacy had better compliance with self-care activities, periodic checkups, better glycemic control, and less occurrence of complications [22]. Our study revealed that patients with a higher overall score, morbidity score, and mortality score had their blood sugar levels in the normal range compared to patients with lower scores which was statistically significant (Table 6). Our results are following that of a few other studies [18,23,24].

Periodic checkups of blood sugar, HbA1c, and other blood parameters which are likely to be deranged in Diabetes like lipid profile, serum creatinine, and urinary protein/albumin, indicative of micro and macrovascular complications an integral part of the management of the disease and prevention as well as early diagnosis of complications like nephropathy and neuropathy. For routine checkups, adequate

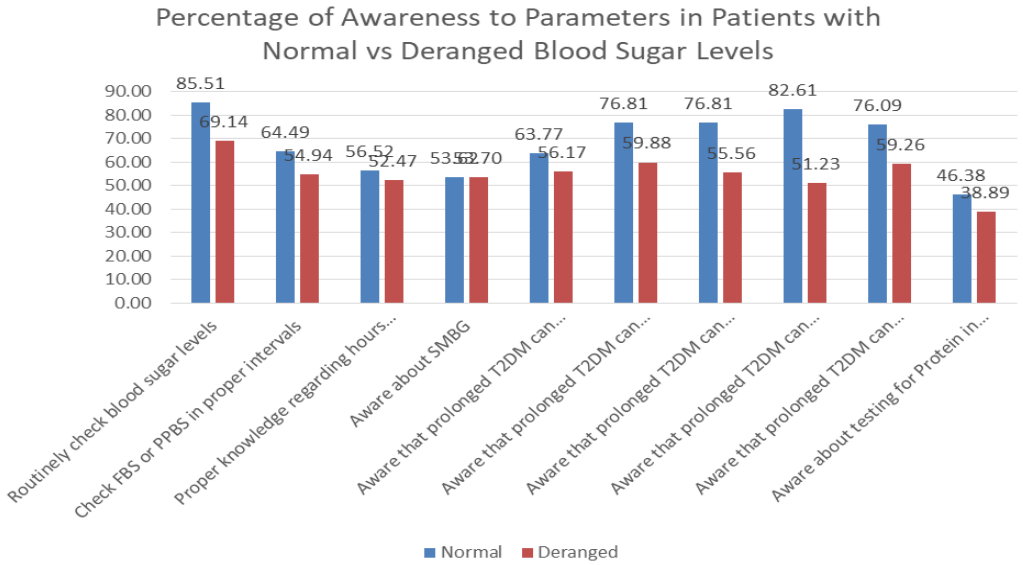


**Figure 1:** Percentage of Awareness to Parameters in Patients with Normal vs Deranged Blood Sugar Levels.

**Table 7: Recommended schedule for laboratory and clinical investigations in Type 2 Diabetes Mellitus patients**

| Time of visit | Laboratory and clinical investigations | | | | | | |
|---|---|---|---|---|---|---|---|
| | FBS PPBS | HbA1c | Fasting Lipid Profile | Renal Function Test | Liver Function test | Foot and retina check up | ECG |
| Index Visit | √ | √ | √ | √ | √ | √ | √ |
| Once in 3 months | √ | √ | × | × | × | × | × |
| Once in 6 months | √ | √ | √ if abnormal at the index visit | × | × | × | × |
| Annual check-up | √ | √ | √ | √ | √ | √ | √ |

health education is essential which has to be provided by the health care givers. Other compounding factors affecting k nowledge and compliance are education and literacy, age, and duration of disease as documented by various studies [25-29]. In our study, we observed an association between the level of awareness with gender (Table 4). We observed that the Overall score, Monitoring, and Morbidity scores were higher amongst the male participants compared to female participants and the difference was statistically significant. However, proper awareness about routine periodic checkups of blood parameters is highly essential as diabetic Mellitus is a self-managed disease needing innate drive for effective self-management. Proper knowledge about the disease process and its associated complications and adopted methods of self-care regimens for proper management of the diseases and prevention as well as early diagnosis of complications is associated with better outcomes and quality of life. As health care providers, it is necessary to be aware and educates the patients regarding the laboratory investigation necessary as per standard guidelines for proper management of the disease which is very commonly associated with many metabolic derangements (Table 7).

## Conclusions

Our study revealed a disparity between awareness and compliance regarding periodic laboratory investigations associated with Diabetes mellitus. Patients were more aware of complications but not of periodic relevant laboratory investigations as part of self-management regimens. Patients with better awareness scores were having their blood sugar in a normal range. Hence, as advocated by various associations, Diabetic health literacy is important for self-care activities but that proper compliance with the self-care activities is also to be monitored and followed diligently.

## Declaration

"I confirm all patient/personal identifiers h ve been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story."

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