Original Article

Pre-Test Preparation of Patients for Plasma Glucose Estimation: Are We Doing Enough?

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Abstract

Background: Proper patient preparation is critical for minimizing pre-analytical errors in laboratory testing, yet this aspect is not thoroughly explored. Factors related to both patients and healthcare professionals (HCPs) can significantly impact the accuracy of test results. This study aimed to assess gaps in patients' understanding and to evaluate the knowledge and communication amongst healthcare professionals regarding pre-test preparation for plasma glucose estimation.

Materials and Methods: This observational, questionnaire-based, cross-sectional study involving patients and healthcare personnel (HCPs) was conducted in the Department of Biochemistry in a tertiary care hospital. The sample size was calculated using the equation: $n = Z\alpha^2pq / L^2$. The recruitment was from both state and private hospitals and laboratories in the region. Separate questionnaires for patients and HCPs were used. Data was represented as counts and percentages.

Results: A total of 100 patients and 50 HCPs were recruited from the blood collection centers of government hospitals (57% & 84%) and private laboratories (43% & 16%). Among patients, there was poor understanding of instructions for fasting and post-prandial samples. Only a few patients understood and/or were compliant with instructions related to fasting state (18%), diet (6%), drug intake (39%), smoking (14%), and post-prandial sampling (5%). Though HCPs instructed patients to come in a fasting state (98%), they had poor knowledge regarding various other aspects of patient preparation.

Conclusion: Patient preparation was affected due to a lack of proper instructions or poor understanding by the patients. This study highlights many lacunae in knowledge as well as communication that need to be addressed while preparing patients for plasma glucose tests. It emphasizes the need for regular capacity-building exercises and continued medical education modules for HCPs as per international standards. The training modules should also emphasize enhancing communication skills.

Keywords:

Pre-analytical phase, blood glucose, Diabetes Mellitus, healthcare professionals, patient compliance, pre-test preparation

Introduction

The high prevalence of diabetes mellitus (DM) in India has resulted in India being categorised as the "diabetic capital of the world" [1]. Estimation of plasma glucose plays a pivotal role in the diagnosis of DM. Laboratory medicine plays an integral role in this era of evidence-based medicine. Therefore, the reports for plasma glucose need to be reliable and unequivocally valid. Although with automation, the field of laboratory medicine has advanced in leaps and bounds, the errors are not completely eliminated. All phases of the laboratory system, i.e., pre-analytical, analytical, and post-analytical phases, have potential sources of errors. Of these, the pre-analytical phase constitutes the majority of laboratory errors [2,3,4]. Proper patient preparation is a vital and indispensable element for reliable results of plasma glucose estimation.

The American Diabetes Association (ADA) and WHO are actively involved in the development and dissemination of stringent guidelines for diagnosis and patient care standards [5,6]. The criteria for the diagnosis of diabetes are defined based on fasting and postprandial glucose levels carried out in blood samples collected from patients prepared in an ideal manner according to the guidelines [5].

In a country like India, a substantially significant number of patients suffering from DM also deal with problems associated with illiteracy, poverty, geographical variations, and language barriers. Evidence suggests that many patients do not come adequately prepared for laboratory investigations [2]. Possible reasons for this may be: (a) poor understanding and compliance of patients; (b) a gap in information and its dissemination by health care personnel (HCP). Hence, the current study is designed to assess the problems associated with the pre-analytical preparation of patients.

Materials and Methods

Study Design

The study was conducted in the Department of Biochemistry, in a tertiary care hospital. It was an observational cross-sectional study involving two groups. The first group of participants comprised the patients/individuals who came to the blood collection center for the estimation of plasma glucose. The second group consisted of HCP, comprising doctors prescribing the tests and paramedical staff involved in sample collection and conducting the tests. Sequential participants who agreed to be part of the study were recruited from each center. The study was carried out in accordance with the Declaration of Helsinki and was ethically approved by the institutional ethical committee (ethical approval no. [2019/0005]).

Sample size: For this study, the sample size was calculated using the equation: $n = Z\alpha^2pq / L^2$

where $Z_{0.05} = 1.96$. For patients, the percentage of prevalence (p) was taken as 50%, representing the maximum variability and ensuring a conservative estimate. q = 100 - p, considering L (Allowable error) as 10%, a sample size of 96 (≈ 100) was found to be adequate. For health care personnel, taking p = 10% and L (Allowable error) as 10% based on the assumption as per experience, a sample size of 49 (≈ 50) was found to be adequate.

The recruitment of the study participants was from both state (02) and private (04) medical colleges, hospitals, and laboratories in and around Nagpur, Maharashtra. The participants were recruited for the study after obtaining written informed consent.

Methodology

Separate questionnaires were prepared for both groups—one for patients and another for health care personnel (HCP) working in

the clinical departments of the hospital and laboratory services. Both questionnaires covered similar attributes of patient preparation. The questionnaires were prepared in English, Hindi, and the vernacular language, i.e., Marathi. The translated versions were pretested on 10 individuals, and modifications were made based on feedback. Bilingual staff assisted participants where necessary.

The questionnaire for HCP was tested by administering it to resident doctors, interns, and phlebotomists. First-year MBBS students who had visited any blood collection center to accompany their relatives or friends, or for personal testing, evaluated the questionnaire for patients. After obtaining the feedback, the questionnaires were modified to improve language and understandability. As per the feedback, the number of questions was also reduced to make the questionnaire more comprehensive and easily deliverable.

The questionnaire for patients comprised questions to assess whether they were well informed, whether they understood the instructions, and their compliance with them. The questionnaire for HCP involved questions to assess their knowledge and the problems they faced while imparting correct instructions to patients. All participants were required to fill in their responses in the presence of the investigator. The responses were anonymized to ensure an unbiased analysis.

Statistical Analysis

The data were represented as counts and percentages. Responses for each question were calculated as a percentage of the total respondents.

Results

A total of 100 patients were recruited from the blood collection centres of government hospitals (57%) and private laboratories (43%). The healthcare personnel (n=50) were also recruited from the same institutes, of which 42 (84%) were from government institutes and 8 (16%) were from private laboratories. The study was conducted over a period of 12 months, and patients and HCPs were interviewed based on two different predefined questionnaires.

Analysis of Responses Among Patients

The participants comprised residents from urban as well as rural areas and were from different literacy backgrounds. The socio-demographic status of the patients is depicted in Figure 1. The study found that 81 patients (n=100) came for plasma glucose estimation, 2 patients had come for investigations other than plasma glucose, and 17 patients were not aware of which investigation they had given the blood sample for. Interestingly, out of these 17 patients, 11 (64.7%) were educated up to matric (class 10th) and above. The responses to binomial questions are shown in Table 1.

Instruction for Fasting Samples: As evident from the table, 97 patients informed that they received instructions regarding pre-test preparation (Table 1, item no. 1). According to the data, amongst these 97 patients, 91 participants received the instruction to come on an empty stomach, and 6 were instructed to come after overnight fasting. However, only 22% of the patients were instructed regarding the time for taking dinner/last meal on the night prior to coming to the sample collection centre (Table 1, item no. 2).

Our study also revealed that there was variation in the understanding of the fasting state among the patients (n=100). As depicted in Figure 2, while 12% of the patients "did not know" the meaning of fasting, among the others, there was variation in their understanding with respect to the period and the items to avoid. Sixty-five patients (65%) believed that nothing is to be taken after

rising in the morning, and 18% understood that one cannot eat or drink anything in the last 8 hours before the test, except water. For 5% of patients, fasting meant not taking even water in the last 8 hours.

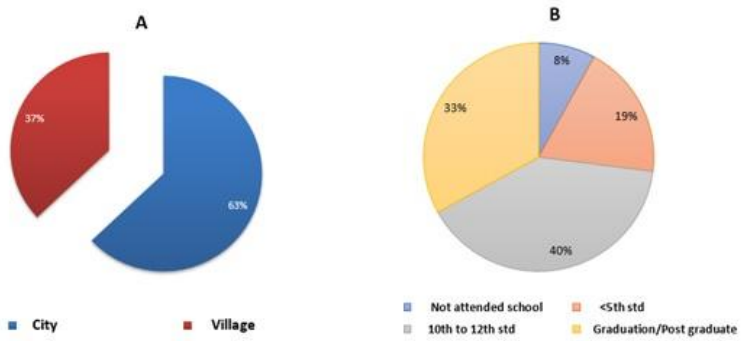

Figure 1: Socio-demographic status of the patients (n=100). A. Residential Status : 63% of the patients were residents of cities and 37% were from villages. B. Educational Status : 8% did not attend school, 19% studied upto 5th standard or below, 40% of the patients attended school between class 10th-12th, and 33% of the patients were graduates or post graduates.

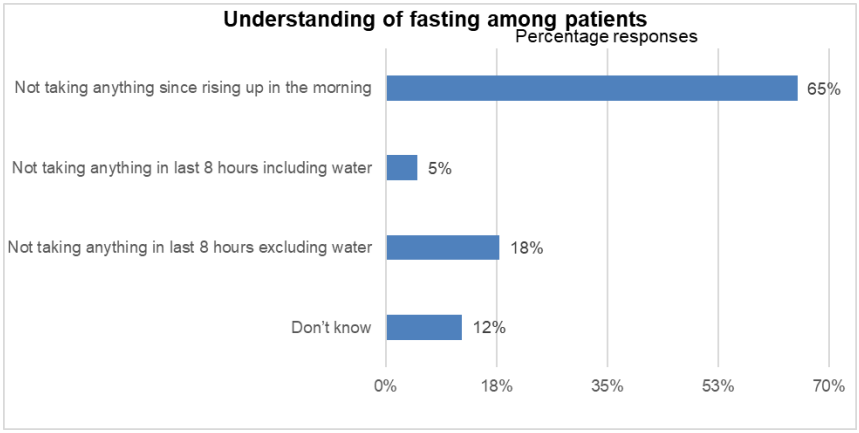

Figure 2: Understanding of fasting among patients that came for plasma glucose testing.(n=100). Results expressed as percentage of responses. 65% understood fasting as taking nothing after rising up in morning, for 5% fasting meant the cannot take even water in

As per our data, it was interesting to note that only 7 out of 63 city residents and 11 out of 37 village residents comprehended the instruction properly. Regarding specific instructions about the intake of milk/tea/coffee/fruit juices before coming for the test (Table 1, item 3), only 41 patients chose the option indicating that they were instructed regarding the same. To evaluate the type of instruction they received, specific questions were asked. Out of these 41 patients, 36 participants stated that they were informed that only water could be taken before giving a fasting blood sample, whereas 5 patients chose the option indicating that they could take items like tea, coffee, and juice. Thus, it is evident from the data that a total of 64% of patients were either not informed or had incorrect understanding, indicating a lacuna in information and understanding.

To determine whether patients consciously change their diet when tests for their glycemic status are planned, we asked about food

intake on the previous night. We found that most of the patients (94%) took their usual meal.

Drug Intake: We also tried to determine if the patients received any instructions regarding taking their regular medications before coming for fasting state blood glucose testing (Table 1, item 4). We found that only 49 out of 100 patients (49%) received instructions. The detailed analysis of their understanding is given in Figure 3, which indicates that 10 patients who were on hypoglycemic drugs did not comprehend the instructions. The data thus suggests that a total of 61% of patients were either not informed or did not clearly understand the instructions.

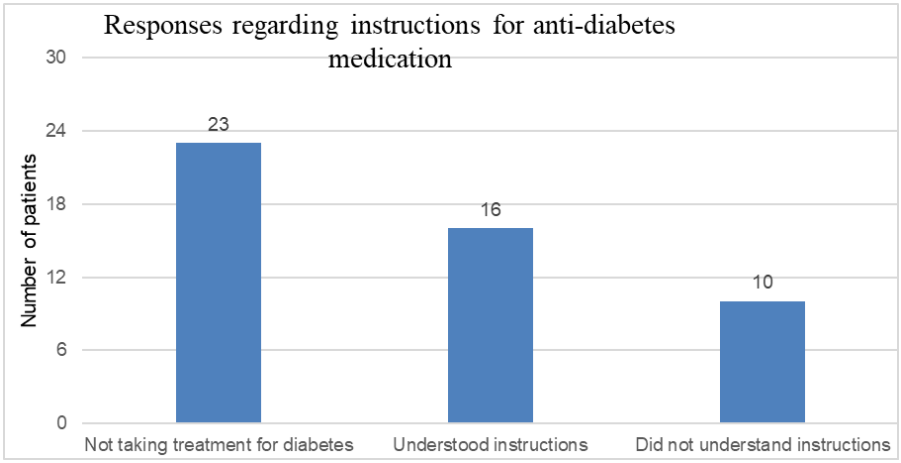

Figure 3: Analysis of patients among those who received any instructions about time of taking anti-diabetic medications before the test. (n=49) 23 patients were not on any anti-diabetic medicines, 16 patients understood the instructions and followed it whereas 1

Smoking: Since smoking affects plasma glucose homeostasis, patients were evaluated to determine whether they received any instructions regarding smoking before giving the fasting and postprandial blood sample (Table 1, item 5). We found that only 14 patients (14%) had received instructions. In order to check whether they understood and followed the instruction, these 14 patients were further asked whether smoking could be carried out before giving a blood sample. While 6 patients were non-smokers, 8 patients responded that smoking should not be done.

Postprandial Samples: We also evaluated patients' understanding of the pre-test preparation for post-meal/postprandial (PP) sampling (Table 1, item 6). Our study found that most patients (77%) took their usual breakfast meal before giving the postprandial blood sample. Three percent of patients took tea and biscuits before giving the sample, 10% had come for a 75g OGTT test, whereas the remaining 10% did not answer the question.

We also analysed the instructions patients received regarding the duration for the PP sample. The results are depicted in Figure 4. While 61% of patients were asked to report to the collection centre after 1.5 hours, 16% were not aware of the duration, and 5% were asked to report after 2 hours.

Assessment of Healthcare Personnel

The healthcare personnel (HCPs) (n=50) were recruited from government (n=42, 84%) and private (n=8, 16%) hospitals and laboratories. These included doctors as well as paramedical staff. There were 29 doctors (58%) (including consultants and resident doctors) and 21 allied health workers (42%), comprising nurses, lab technicians, and phlebotomists. Figure 5 depicts the average

number of patients that were coming to various blood collection centres where the study was conducted.

The HCPs were asked about their view on the effect of patient preparation on test results. Only 33 out of 50 (66%) responded that proper patient preparation is critical for accurate results. The rest of the HCPs either believed that there was no or only a slight effect on the reliability of results (n=11, 22%) or did not answer (n=6, 12%). The cadre-wise results are depicted in Figure 6.

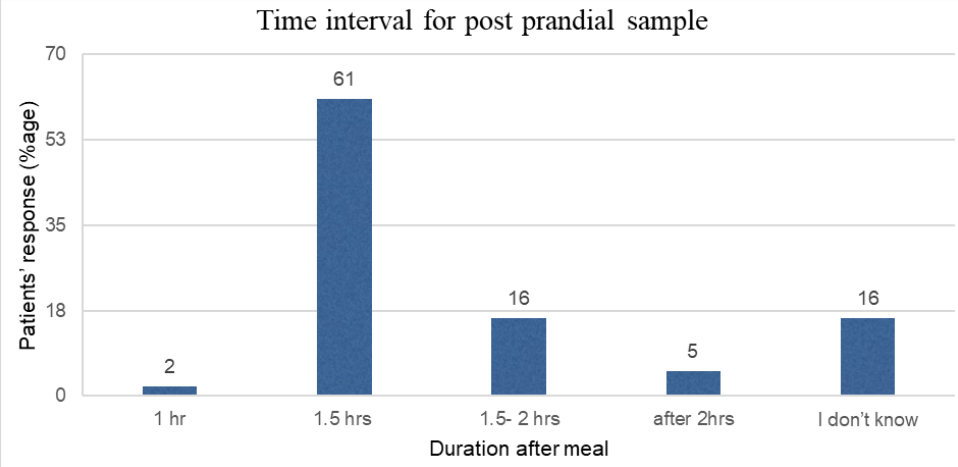

Figure 4: Instructions patients received about the time interval for giving the post prandial plasma glucose sample. (n=100). Results expressed as percentage of responses. 61% were asked to come 1.5hrs after having meal, 16 % were called between 1.5-2 hrs after meals, 5 % were asked to come after 2 hrs of taking meal, 2 % were called 1 hr post meal. 16% chose the option of "do not know."

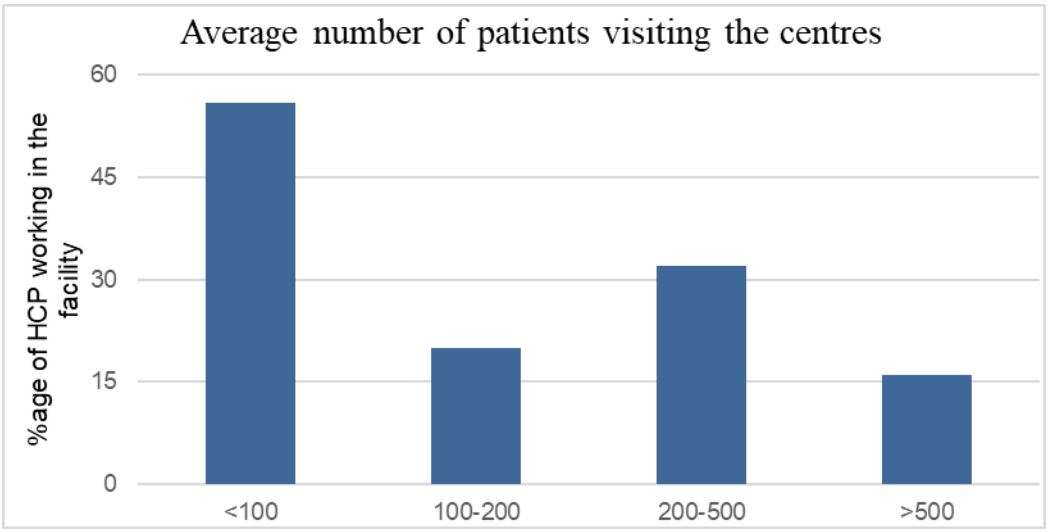

Figure 5: Average number of patients that were coming for blood testing at the centres where the study was conducted. 56% of the healthcare workers worked in the facility where less than 100 patients come daily, 20% worked in facility where 100-200 patient visited whereas 32% healthcare workers were from setups were 200-500 patients visited and 16% worked in facility where more than 500 patient visited daily.

Fasting Samples: Regarding fasting blood glucose testing, 49 out of 50 HCPs responded that they gave instructions for patient preparation (Table 1, item 7). The patients were instructed to come in a fasting state for plasma glucose analysis by all HCPs

(Table 1, item 8). Almost all participants (48 out of 50) stated that they explained the meaning of the fasting state to the patients (Table 1, item 9). Almost all HCPs (49 out of 50) ensured that instructions were understood by patients (Table 1, item 11), and compliance was ensured by 45 HCPs (Table 1, item 12).

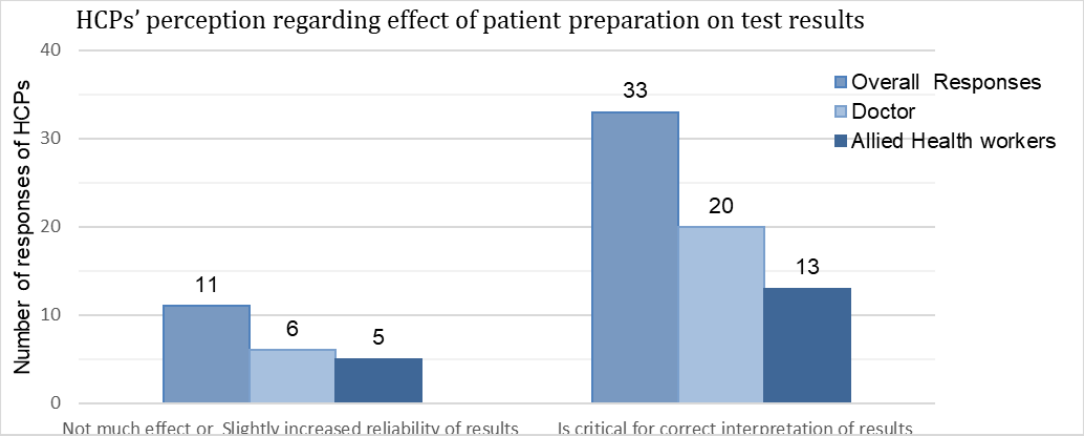

Figure 6: Healthcare workers view on effect of patient preparation on test results. Figure depicts the distribution of responses among, doctors and allied health workers (n=50) who were interviewed. 6 Health care workers did not respond to this question.

To assess the knowledge of HCPs regarding the duration of fasting required before blood sampling, we asked about the number of hours of fasting needed. As depicted in Figure 7, 36 HCPs (72%) chose the option of 8–10 hours of fasting, whereas 12 participants (24%) opted for more than 12 hours of fasting. Two doctors did not respond to the question.

Postprandial Sampling: Questions were also asked to assess the understanding and type of instruction given to patients regarding post-meal sampling. Forty-one out of 50 (82%) HCPs instructed patients to observe 2 hours after the end of the meal. Twelve percent instructed their patients to count 2 hours from the start of the meal, whereas 6% instructed patients to count the 2-hour duration from the time of giving the fasting sample, indicating non-uniformity in HCP knowledge (Figure 8).

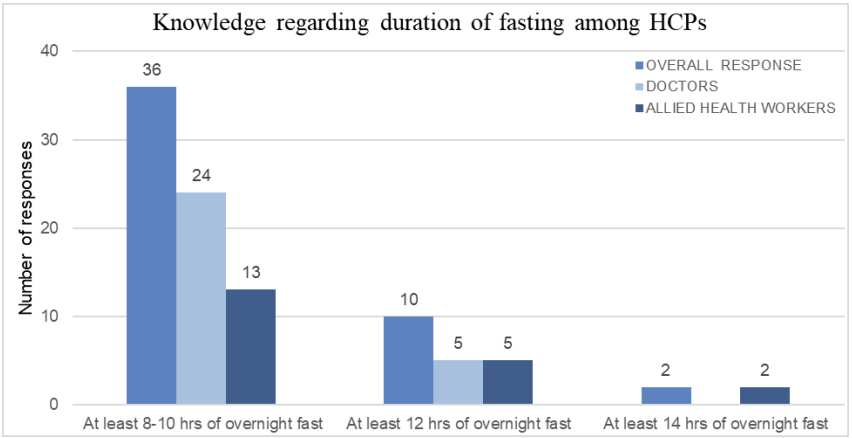

Figure 7: Instructions given regarding number of hours of fasting that was needed by the patients coming for fasting plasma glucose testing. (Total number of HCPs = 50). Figure depicts overall responses of HCP as well as distribution of responses among doctors and allied health workers. 02 HCPs did not respond.

Drug Intake and Smoking: Only 26 (52%) HCPs ensured taking a history of drug intake (Table 1, item 13). Regarding smoking instructions, 46% (n=23) of HCPs provided instructions, 46% did not, and 8% (n=4) did not respond.

In our study, 94% of HCPs stated that fasting and PP blood samples should be collected on the same day, while 6% believed they could be taken on different days.

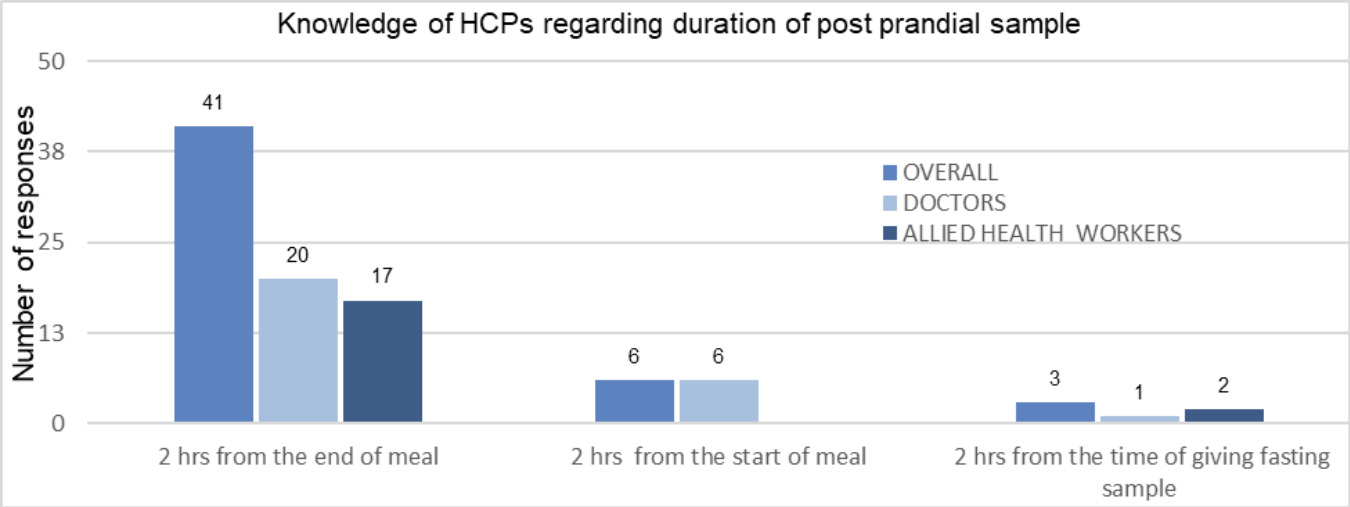

Figure 8: Distribution of responses among doctors and allied health workers for instructions they give regarding the duration after which the patient has to come to give postprandial sample. Figure depicts overall responses of HCP as well as distribution of responses among doctors and allied health workers.

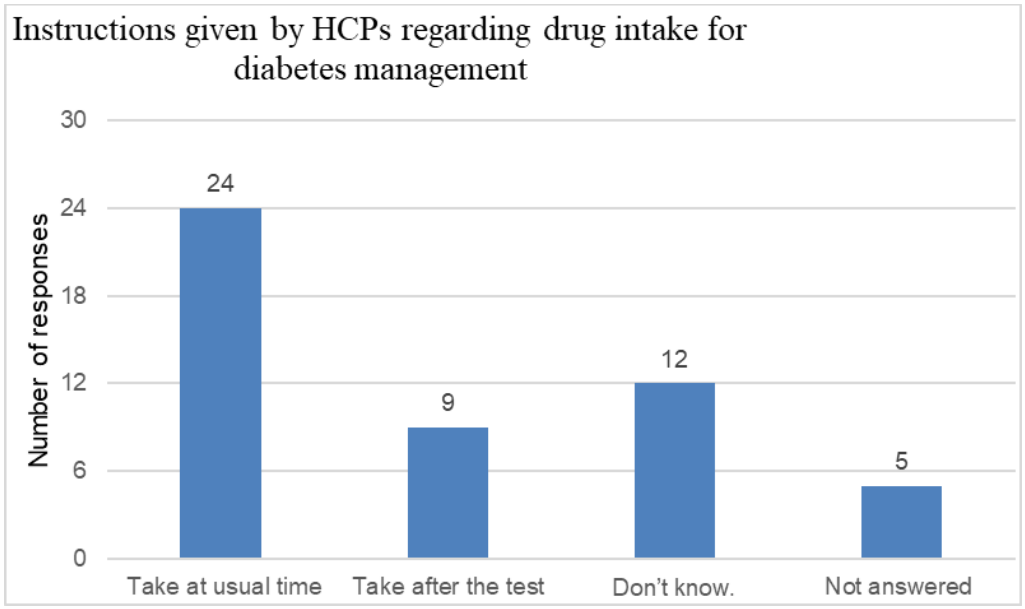

Figure 9: Responses of HCP regarding the instruction they give to the patients about taking diabetes medication when they come to give fasting plasma glucose sample. (n=50). 24 HCP (48%) told that medication should be taken on usual time , 9 (18%) told that it should be taken after the fasting blood sample is collected. 12 (24%) Did not know the answer and remaining 5 (10%) did not answer the question.

Table 1: Summary of the responses to the patient and healthcare worker's questionnaire.

Item no	Questions	Type of response (in numbers)		
		Yes	**No**	**No answer**
	Analysis of responses among patients (n=100)			
1	Whether any instruction was given regarding preparation before fasting sugar test?	97	3	
2	Have you ever been instructed by anyone regarding the time of dinner on the previous day of the test?	22	77	1
3	Have you ever been instructed by anyone regarding intake of tea/coffee/fruit juices, etc before giving the morning blood sample?	41	49	10
4	Have you ever been asked by anyone regarding routine medications before the test?	49	51	
5	Have you ever been instructed by anyone regarding smoking before or during the test?	15	84	1
6	Have you ever been told by anyone about the time for giving the blood sample after having the food?	85	7	8
	Analysis of responses among Health care providers (n=50)			
7	Do you give the instructions to patients who come to you for fasting glucose testing?	49		1
8	Do you ask the patients to come fasting for glucose testing?	50		
9	Do you explain the meaning of fasting to the patients?	48		2
10	If No for the above question, do you ensure that instructions are given to patients by some other staff before the test?	7		43
11	Do you ensure that these instructions have been understood by the patients?	49		1
12	Do you also ensure the compliance of your instructions by the patients?	45	4	1
13	Do you ask history of drug intake before taking blood sample?	26	22	2
14	Do you think that the fasting and post meal sample should be taken on the same day?	47	3	

Discussion

The pre-analytical phase is the most vulnerable and challenging stage in total laboratory procedures, as it is out of direct control of the laboratory [2,3]. Some major variables that are controllable and can affect the results of laboratory analysis include diet, physical exercise, circadian rhythm, etc. Though important, this phase has been neglected and has not been sufficiently studied. A few studies reported that many times, patients are either not completely aware of the pre-test preparation or they might not follow these instructions completely [7,8]. This questionnaire-based study is an effort to assess the type of instructions imparted to patients as well as to identify gaps in the dissemination of information among patients and healthcare providers (HCPs).

In this study, the education level of most patients (73%) was 10th standard or above, and therefore, it was expected that most patients would be able to comprehend the instructions given before sample collection. The fact that many of them were well-educated provides relevance to this study, where we have tried to understand various deficiencies in the pre-test preparation of patients.

An important area uncovered was communication with patients. Though almost all HCPs reported that they ensured patients

understood their instructions, our results revealed that a large proportion of patients were either not instructed about certain aspects of pre-test preparations or were unable to comprehend the instructions imparted to them.

In spite of the fact that almost all HCPs explained the fasting state to be observed before sample collection, a vast majority of patients (77%) were found to be ignorant. The American Diabetes Association (ADA) recommends a complete fasting state except for water for at least eight hours before giving a fasting plasma glucose sample, and a postprandial sample should be collected after taking a usual carbohydrate load [5]. However, our study reveals that many patients consumed milk, tea, coffee, or fruit juices before giving a sample for fasting glucose. In most places, blood sample collection centers start operating from a particular time of the day. Mentioning the time of dinner can ensure the requisite duration of the fasting state among patients. However, we observed that most patients (78%) did not receive any such instruction. Additionally, many HCPs (24%) were also unaware of the required duration of the fasting state. Besides leading to erroneous results, prolonged fasting can precipitate hypoglycemia in diabetic patients. Therefore, it is imperative that HCPs are educated regarding the meaning of fasting and the need to clearly instruct patients.

A common doubt among patients concerns the intake of prescribed diabetes medications while coming for a fasting glucose sample. Our results showed that an alarming number of patients (51%) did not receive instructions regarding the timing of drug intake. Additionally, our results reveal that, apart from a lack of knowledge, it is also not a routine practice among HCPs to instruct patients regarding this. Moreover, many patients who received instructions reported that they were unable to understand them. This lack of clarity may put the patient at risk of hypoglycemia [9].

Smoking is another important yet neglected aspect of pre-test preparation. Acute smoking is a well-known factor affecting glucose tolerance and insulin sensitivity [10,11]. Yet, we found that only approximately half of the HCPs instructed patients to avoid smoking before giving a blood sample. Additionally, only 14% of the patients reported receiving such instructions. It is evident that smoking and the timing of drug intake are important yet neglected aspects that need to be addressed. Active intervention to educate HCPs in this regard is required so that proper instructions can be imparted to patients.

We also observed gaps in preparing patients for postprandial sampling. It is commonly observed that, before giving postprandial/post-meal blood samples, patients do not take their usual breakfast. In our survey, only 77% of the patients took their usual breakfast. We also observed disparities in the knowledge of HCPs regarding the meaning of a two-hour postprandial blood sugar test. While the majority of HCPs (82%) understood that the time for collecting a postprandial sample should begin two hours after the completion of the meal, others believed the timing should begin either from the start of the meal or after drawing the fasting sample. This aspect is important because insulin reaches peak values within 15–30 minutes of a meal [11], and thus, failing to specify the time duration in which the meal should be completed can lead to erroneous postprandial glucose results. Most patients (82%) reported being instructed to give the postprandial blood sample between 1.5 to 2 hours after the fasting sample.

It is noteworthy that the majority of HCPs in our study were from government hospitals. Therefore, the reason for calling patients earlier than two hours may be due to the long queues in government healthcare setups. However, an important finding of our survey is that a few patients were told to come after one hour of giving the fasting blood sample, and some were not informed of the exact time interval required. This highlights another area that needs to be addressed so that HCPs can provide correct information to patients.

Most healthcare workers (47 out of 50) stated that fasting and postprandial samples must be collected on the same day. However,

to the best of our knowledge, there is no such recommendation by any working group. This has important implications because collecting postprandial samples on a subsequent day could reduce the duration of a patient's stay at the healthcare facility. It is well established that infections can be transmitted in ambulatory care settings [12]. Therefore, a shorter stay would not only improve patient convenience but also reduce exposure to infections.

India is the second most populous country in the world, with a poor doctor-to-patient ratio of 1:1000 [13]. This makes it challenging for doctors and other healthcare workers to adequately inform patients about proper pre-test preparation. It is important to note that difficulties in patient preparation for laboratory tests may vary between public and private healthcare settings. Our study included patients from both settings.

In public hospitals, where patient load is high and human resources are often stretched thin, HCPs face additional challenges in ensuring effective patient engagement and communication. The high patient footfall, especially during peak hours (e.g., 8 a.m. to 12 p.m.), further limits the time for one-on-one interactions, making it difficult for HCPs to thoroughly educate patients. In contrast, private healthcare settings have a better patient-to-provider ratio, and resources may be more readily available. In such settings, HCPs are generally able to provide more personalized care and detailed instructions. However, despite these advantages, patients may still receive insufficient or unclear instructions due to variations in the knowledge and training of healthcare workers. Both public and private healthcare settings face unique challenges. Therefore, targeted interventions such as regular training programs for HCPs and the use of visual aids for patient education could significantly improve the pre-test preparation process in all facilities.

Our study is the first of its kind to expose multiple gaps that need to be addressed in the preparation for basic plasma glucose tests in both fasting and postprandial states. While our data substantiate patients' poor understanding and lack of compliance with instructions, it is also an eye-opener that necessitates steps to educate and train HCPs in accordance with standard guidelines from the ADA or WHO. Additionally, there is a need to sensitize staff regarding effective communication skills.

Our Recommendations: Regular capacity-building exercises should be conducted with existing staff/HCPs to educate and train them in better communication skills. If high patient loads prevent healthcare workers in laboratories from properly communicating, special staff can be recruited to provide this education. Utilizing other modalities such as audiovisual aids, display charts, and structured training modules for HCPs can help in educating both patients and HCPs. These training modules can be disseminated through accessible platforms like Project ECHO and NPTEL for targeted HCP training [14].

Strengths of the Study: Our study is the first of its kind to evaluate the knowledge of both HCPs and patients regarding pre-test preparation from the same centers. This study has high relevance and has identified various gaps in the knowledge and awareness of HCPs, as well as communication gaps with patients.

Limitations of the Study: The study covers a limited geographical area. To assess its broader relevance, other regions of the country should also be evaluated.

Conclusion

This study was conducted to assess the current practices in pre-analytical patient preparation for laboratory glucose estimation. The results indicate the necessity of designing continued medical education modules for clinicians as well as laboratory personnel to keep them updated on the current guidelines. The results will also be helpful in designing patient education programs to decrease the probability of pre-analytical errors, which constitute the major source of errors.

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