SCIENCEFORECAST
A digital science library

Journal of Family Medicine Forecast

Blood Glucose Fasting – Harmonization of Variables Affecting Pre Analytical Phase

Sareen R*, Kapil M and Gupta GN

Department of Pathology, Santokba Durlabhji Memorial Hospital and Research Centre, Jaipur, India

Abstract

Objective: In the era of evidence based medicine laboratories play a pivotal role. Maintaining quality in laboratory results, keeping errors minimum is a daunting task. The preanalytical phase of testing is most error prone as it involves many personnel. The aim of the study was to assess the knowledge and awareness of patients regarding fasting blood glucose level estimation.

Design & Study Participants: A prospective study of all patients visiting laboratory reception for blood glucose fasting for a week time was considered as participant to the questionnaire.

Results: Among the 200 outdoor adult patients enrolled for study, 138(69%) believed that 12 hour fasting with water was the most appropriate for fasting blood glucose estimation. 14(7%) followed a 8 hour fasting time frame, 24(12%) didn't consume water during overnight fasting where as 14(7%) consumed tea or coffee or juice in morning prior to sampling and 8(4%) had breakfast in the morning.

Conclusion: The study shows that there are areas of improvement regarding the understanding of fasting requirement, need of fasting for other tests, dietary modifications preceding test and maximum allowable water intake. These issues are not clearly mentioned in literature or guidelines are there is heterogeneity in the world leading to development of local regional guidelines which needs harmonization. Proper training to staff, education and awareness of patients is the most prudent approach to minimize preanalytical errors thereby enhancing quality of laboratory results adding to better patient care.

Keywords: Preanalytical errors; Fasting glucose; Questionnaire

OPEN ACCESS

Introduction

Laboratory services are the backbone of today's evidence based medicine era. Laboratory quality is to be maintained by precision, accuracy and speed of reports delivered to the patients. The rapid advancement of technologies lead to improvement in laboratory services, but in spite of all automated machines and quality control processes errors do occur. The laboratory errors can occur at any three phases of laboratory cycle that is preanalytical, analytical and post analytical phase. The preanalytical phase entails selection of the test to be ordered test prescriptions patient preparation followed by collection, handling, transportation, preparation and eventually storage of the specimens, analytical phase is limited to sample testing whereas and post analytical phase consists of results reporting, interpretation and release of reports maintaining turnaround time [1]. The frequency of laboratory errors is more in preanalytical phase followed by analytical and post analytical phase [1,2]. The medical treatment is based upon results obtained from the laboratory and because of that it is crucial for patients to get most accurate information [3]. The preanalytical phase is known to be the error prone zone because it is handled by many personnel[2]. Inadequate instruction about preanalytical preparation and lack of knowledge in patients will lead to error especially fasting blood glucose results. Appropriate preparation of the patient for blood sampling is of vital significance for the quality of the test results. Suboptimal information to patient about preanalytical phase and lack of compliance of the instruction by the patients will lead to erroneous results [4]. Our study aims at assessing the preanalytical preparation from outpatients for fasting glucose estimation in our institute.

Materials and Methods

We conducted a prospective study at our hospital which is a community hospital in western India. The study group included all adult outpatients who were advised fasting glucose level

Table 1:

	Questionnaire			
1	Gender	·	Male	98 (49%)
		·	Female	102 (51%)
2	Age (Years)	·	<25	10 (5%)
		·	25-50	40 (20%)
		·	50-65	78(34%)
		·	>65	72 (36%)
3	Meaning of fasting for patient	·	Nothing to eat or drink	24(12%)
		·	12 hours & allowed to drink water	138 (69%)
		·	8 hours and allowed to drink	14 (7%)
		·	Tea / Coffee/ Juice in morning	14 (7%)
		·	Breakfast can be taken in morning	8 (4%)
		·	Do not know	2(1%)
4	Is it needed for all tests	·	Yes	40 (20%)
		·	No	112(56%)
		·	Don't know	48(24%)
5	Are you fasting right now?	·	Yes	184(92%)
		·	No	12(6%)
		·	Don't know	4(2%)
6	When did you have your meal last time?	·	Before 10 hours	32 (16 %)
		·	Before 12 hours	152 (76%)
		·	Before 18 hours	6 (3%)
		·	Before sample collection	4 (2%)
		·	More than 18 hours	4 (2%)
		·	Don't know	2 (1%)
7	When did you consume liquid last time?	•	No fluid since morning	80 (40%)
		•	With water in morning	50 (25%)
		•	Juice/Coffee/ Tea / Milk in morning	62 (31%)
		•	Solid eatables	6 (3%)
		•	Do not know	2(1%)
8	Did you change your dietary habits 2-3 days before coming to laboratory?	•	Yes	74 (37%)
		•	No	124(62%)

estimation attending the designated sample collection area of laboratory. The study included all male and female patients. The consent for participation in the study was taken .We assessed the knowledge and awareness of patients about fasting preparation for glucose level estimation using a questionnaire. The questionnaire (Table 1) was designed in both languages English and Hindi (local language) to assess the awareness level and also compliance of patients in following instructions for fasting glucose testing.

A total of 200 adult patients over a week's time period reaching the sample collection area between 9.00AM and 5.00PM were enrolled in study. These patients were all outdoor patients with no other tests recommended other than fasting glucose. The questionnaire was targeted to determine- understanding of patient regarding fasting blood glucose level, source of information to patient and status of patient at the time of sample collection.

There were 102 (51%) females and 98 (49%) male subjects in the study (Table 1). The age and sex wise distribution of participants are shown in Figure 1 & 2. When patients were asked about the correct definition of fasting blood glucose (no food intake for 12 hours preceding blood testing, only water intake allowed) only 138(69%) patients were fully aware while 62(31%) patients of study group interpreted it in an appropriate manner (Figure 3). Patients had different views regarding fasting definition- 138(69%) believed that 12 hour fasting was required for test, 14(7%) thought the duration of fasting to be 8 hours, 14(7%) patients consumed tea or coffee or juice before sampling, 8(4%) patients had morning breakfast after overnight fasting, 24(12%) patients didn't consume even water in the past 12 hours and 2(1%) were unaware and didn't know about the requirement. The source of information for fasting requirement was provided by doctor in most of the cases 138(69%),nursing staff in8 (4%), laboratory person 2(1%) and signage displayed at laboratory reception in 2(1%) cases. 6(3%) patients got information from internet sources and 18(9%) had previous knowledge of fasting requirement. Three were 26(13%) patients who could not recollect the source of information (Figure 4). There were 80(40%) patients who did not consume any liquid since past 12 hours. 62(31%) patients consumed coffee, tea or milk and 6(3%) has solid food within 12 hours of testing
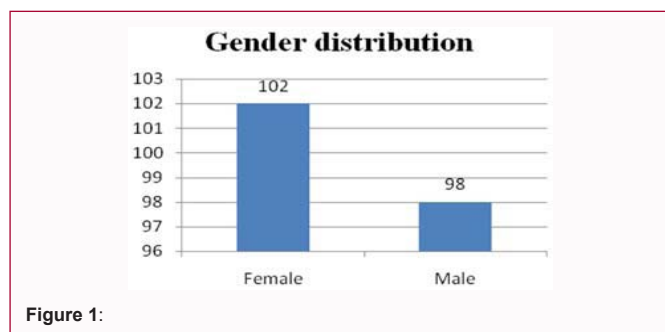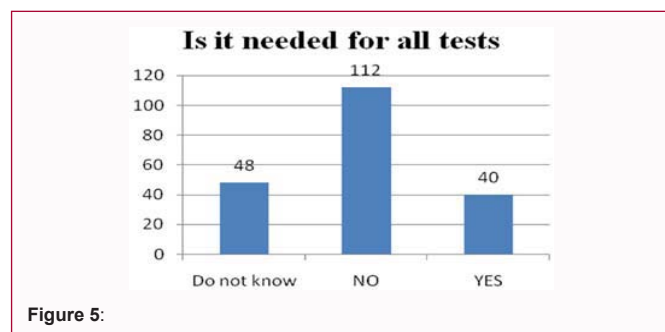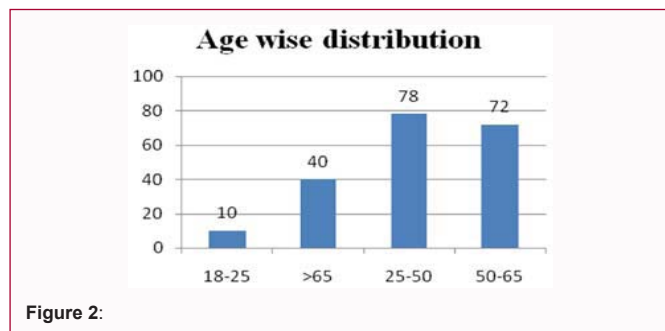
Figure 1:

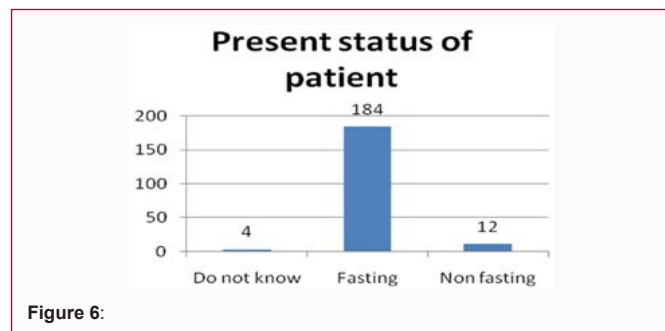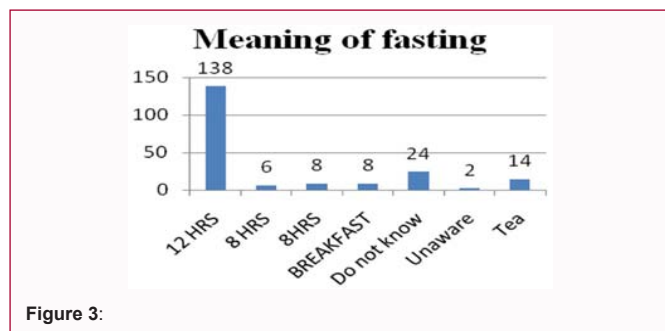**Figure 2**:

Figure 3:

Figure 4:

Figure 5:

Figure 6:

(Figure 5). There were 50(25%) patients who took water only in past 12 hours as per the guidelines for fasting glucose testing. 74(37%) patients reported change in dietary habits in days preceding testing (Figure 6). 40(20%) patients believed that the fasting requirement is for all tests apart from glucose fasting testing (Figure 7). 184(92%) patients believed that they were true fasting as per their knowledge of the subject (Figure 8).

Discussion

Every laboratory test has three phases- preanalytical, analytical & post analytical phase. The preanalytical phase comprises of test orders, patient preparation, blood sampling and sample transport [5]. This phase of testing involves many personnel and is thus prone to maximum errors [6]. Studies in literature have shown low adherence to standardized practice in preanalytical phase. The present study shows that there is lack of patient awareness regarding fasting glucose testing requirement. Unfortunately, the problem is far graver than what it appears. It is attributed to the lack of standardized and harmonized procedures all over the world [7-10]. Let us examine few points pertaining to the testing preparation.

Definition of fasting [11]

The recommended time for fasting varies from region to region based on local guidelines. For instance, in US, UK, the fasting interval is of 8 hours whereas in Australia & other European countries it is 8-10 hours, in Germany it is of 12 hours. The existing guidelines and recommendations leave exact fasting time within jurisdiction of every single institute. The practice of 12 hour fasting is to cover the requirement for lipid profile testing which essentially requires 12 hour of fasting where as for fasting glucose the requirement is of 8 hours only but since the two tests are often ordered together the fasting time for glucose is exaggerated.

Water intake

There is no recommendation regarding the maximum allowable volume of water an individual can consume before the day of testing and during 8 hour fasting interval. One has to assume that the ingested volume of water mirrors usual daily water intake [12]. Even the WHO guidelines on drawing blood based on best practices in phlebotomy do not clarify on the volume of water permitted in fasting interval [13].

Diet restriction

The clinical & laboratory institute (CLSI) H21 guideline also does not mention patient preparation in terms of fasting requirement. The guideline mentions that appropriate time & diet restrictions apply to certain tests but they do not specify exactly about requirement of dietary restriction on fasting patients [14].

Time of sampling

Fasting 8 hour is prerequisite for fasting blood glucose estimation

but there is lack of guidelines on the time of sample collection which is generally between 7:00AM to 9:00AM. Theoretically if there are no diurnal variations, overnight fasting is not required. It is however more convenient to fast during night than in day time. The test order generally accompanies other tests which have their reference range values for 7:00AM to 9:00AM and drawing blood samples at other time may affect interpretation [15,16].

Patient compliance with testing recommendation

In a developing country like India with low literacy level there are lack of patient awareness and knowledge about the fasting glucose estimation test requirement.

It is seen in the study that 68(32%) out of 200 patients were not able to follow recommendations. Either they consumed coffee, tea or meal rendering them unfit for sampling. The information was provided by doctor- senior doctor or junior doctor in 138(69%), laboratory person & laboratory signage in 2(1%) each, 18(9%) relied on self knowledge whereas 3(6%) on internet sources (Table1). Of all those patients who were informed by doctor 38(27%) could not properly comprehend the meaning of fasting glucose requirement. Among patients who relied on self knowledge 10(55.6%) were not true fasting. The study highlights the lacunae in patient doctor communication, lack of information on part of patients which eventually will cause unreliable laboratory result. The study shows that there is large proportion of patients who were not familiar with the requirement of fasting state.

The striking feature of our study is that the knowledge and information given by the doctor did not significantly affect patient behavior towards testing. Of the 138 patients informed by the doctor, 34(24.64%) believed that fasting requirement is needed for all tests and another 34(24.64%) had no knowledge of the requirement of fasting for other tests. It was 70(50.72%) of patients amongst those informed by doctor who were properly aware of fasting requirement for other laboratory tests.

It is the responsibility of all stakeholders who are involved in the testing process requesting physician, nurse, laboratory technician , phlebotomist to give appropriate time and maintain proper communication with the patient as these two were the confounding factors requiring major improvement as suggested by other studies in literature [17].

Laboratories in particular the one which are compliant with ISO15189 [18], JCI maintain clear understandable written instructions for display to patients at laboratory sample collection area. But unfortunately as shown in our study there were only 2(1%) of patients who read the information. Ultimately it is the task of laboratory to create public awareness about preanalytical phase and motivate patients to seek information in required cases [19].

The questionnaire like those in our study should be incorporated in quality indicators of laboratory so that corrective actions are taken to improve information provided to patients regarding patient's preparation for laboratory testing [20].

The quality of health care delivered to population relies on the education and awareness of the people. Adequate patient education is hallmark of good health care. There are numerous articles, guidelines and educational material available in the literature but few of them discuss their effectiveness. The paper highlights the deficiency in patient awareness as elucidated by their knowledge for a basic test preparation like fasting blood estimation. The prescribing doctors constitute first point of contact with the patient. They share unique relationship with patients earning their trust and so patients take their advice seriously with utmost sincerity and great compliance [21]. There is no doubt that putting entire responsibility of patient education on prescribing doctors is not justified nor is practical with the increased workload and time constraints. The emphasis should be on team work involving clinician, nursing staff, laboratory staff and pathologist in making an impact on patient education. Correct Education is the key to success and will discourage repeat unnecessary tests/referrals that are time consuming and non cost effective. The true satisfaction to the profession lies in patient education and then only we will be doing justice to the literal meaning of being a doctor i.e *to teach. (Derived Latin word docēre).*

Conclusion

The heterogeneity in the sample collection together with patient adherence is a complex issue leading to huge burden on our healthcare system reported worldwide which warrants immediate harmonization. We have provided a simplistic overview of methodologically proven adherence-enhancing strategies so that the research can be translated and applied to patient care settings. Involving multiple stakeholders and other healthcare providers, in addition to physicians, may help reduce the time and cost involved with implementing these strategies. The most prudent approach is through proper training to medical and paramedical staff regarding preanalytical variable on patient preparation for fasting blood glucose estimation. It is important to develop questionnaires and other tools to evaluate the effectiveness & compliance of patients for specified test. The dictum is 'educate, aware & motivate', patients to avoid erroneous results dispatched by laboratory.

Bibliography

1. Schiff GD, Hasan O, Kim S, Abrams R, Cosby K, Lambert BL, et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. Arch Intern Med. 2009; 169: 1881 –1887.

2. Najat D. Prevalence of Pre-Analytical Errors in Clinical Chemistry Diagnostic Labs in Sulaimani City of Iraqi Kurdistan. PLoS ONE. 2017; 12: e0170211.

3. Plebani M. Exploring the iceberg of errors in laboratory medicine. Clin Chim Acta. 2009; 404: 16-23.

4. Lippi G, Guidi GC, Mattiuzzi C, Plebani M. Preanalytical variability: the dark side of the moon in laboratory testing. Clin Chem Lab Med. 2006; 44: 358-365.

5. Simundic AM, Lippi G. Preanalytical phase - a continuous challenge for laboratory professionals. Biochem Med. 2012; 22: 145-149.

6. Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Biochem Rev. 2012; 33: 85-88.

7. Bilic-Zulle L, Simundic AM, Supak Smolcic V, Nikolac N, Honovic L. Self reported routines and procedures for the extra-analytical phase of laboratory practice in Croatia —cross-sectional survey study. Biochem Med. 2010; 20: 64–74.

8. Simundic AM, Bilic-Zulle L, Nikolac N, Supak-Smolcic V, Honovic L, Avram S, et al. The quality of the extra-analytical phase of laboratory practice in some developing European countries and Mexico — a multicentric study. Clin Chem Lab Med. 2011; 49: 215–228.

9. Simundic AM, Cornes M, Grankvist K, Lippi G, Nybo M, Kovalevskaya S, et al. Survey of national guidelines, education and training on phlebotomy in 28 European countries: an original report by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group

for the preanalytical phase (WG-PA). Clin Chem Lab Med. 2013; 51: 1585–1593.

10. Wallin O, Söderberg J, Van Guelpen B, Stenlund H, Grankvist K, Brulin C. Blood sample collection and patient identification demand improvement: a questionnaire study of preanalytical practices in hospital wards and laboratories. Scand J Caring Sci. 2010; 24: 581–591.

11. Simundic AM, Cornes M, Grankvist K, Lippi G, Nybo M. Standardization of collection requirements for fasting samples: for the Working Group on Preanalytical Phase (WG-PA) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). Clin Chim Acta. 2014; 432: 33-37.

12. Naumann J, Biehler D, Lüty T, Sadaghiani C. Preventing Diabetes—What Is the Potential of Daily Water Intake and Its Mineral Nutrients?. Preprints. 2017; 2017070012.

13. WHO guidelines on drawing blood: best practices in phlebotomy. Geneva: World Health Organization; 2010.

14. Clinical Laboratory Standards Institute. Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays: approved guideline — sixth edition. CLSI document H21-A5. Clinical and Laboratory Standards Institute: Wayne, PA; 2008.

15. Clinical Laboratory Standards Institute. Procedures for collection of diagnostic blood specimens by venipuncture; approved guideline — sixth edition. CLSI document H3-A6. Clinical and Laboratory Standards Institute: Wayne, PA; 2007.

16. Emberson JR, Whincup PH, Walker M, Thomas M, Alberti KG. Biochemical measures in a population-based study: effect of fasting duration and time of day. Ann Clin Biochem. 2002; 39: 493–501.

17. ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory I. *Clinical biochemistry*. 2009; 42: 274-278.

18. Lippi G, Becan-McBride K, Behúlová D, Bowen RA, Church S, Delanghe J, et al. Preanalytical quality improvement: in quality we trust. Clin Chem Lab Med. 2013; 51: 229-241.

19. EC Aggregate report: 2017.

20. Lillo R, Salinas M, Lopez-Garrigos M, Naranjo-Santana Y, Gutiérrez M, Marín MD, et al. Reducing preanalytical laboratory sample errors through educational and technological interventions. Clin Lab. 2012; 58: 911-917.

21. O'Kane Maurice John, Lopez Berenice. Explaining laboratory test results to patients: what the clinician needs to know. BMJ. 2015; 351: h5552.