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"PLASMA VENOUS GLUCOSE ESTIMATION - THE UNTOLD STORY"

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ABSTRACT

Introduction: Plasma venous Glucose estimation is one of the most commonly asked investigation in a clinical setting. This test has a lot of pre-analytical variables affecting the final result, and patient participation in providing sample is very essential. The present study was undertaken to determine the quality of pre-analytical errors caused by the patients while giving their sample and quantify them. Material and Methods : A total of 400 cases were interviewed on the quality of the sample provided by them for analysis of plasma venous glucose. The interview was done after the post prandial sample had been collected. The nature of fasting, the timing between the fasting and the post prandial sample, the nature of exertion undertaken between providing the two samples and the history of taking medications was specifically looked into and any deviations from the correct procedure was considered as an error. Results: Of the 400 cases interviewed, only 138 patients had given a proper fasting and post prandial sample. Nearly 34% of the post prandial samples were not collected on time. Also 24% of the samples had more than one pre-analytical error in it, which could have significantly affected the final glucose results. Conclusion: There are a lot of pre-analytical errors that are being created by the patients while giving the samples for plasma venous Fasting and Post prandial glucose estimation. These errors are not being specifically looked for and hence going undetected. The aim of this article is to sensitise health care workers on the magnitude of these errors and suggest methods to reduce them.

KEYWORDS: Pre Analytical errors, Glucose estimation, errors contributed by patients, fasting, postprandial, exercise.

INTRODUCTION

India has dubiously earned the title of being the diabetic capital of the world, a title aggressively being competed by China. Large numbers of fresh cases of diabetes are being detected every year in this country. Diagnosis of cases of diabetes and their management in the modern era is evidence based. There are strict guidelines for diagnosing new cases, choice of medicines to be offered to diabetics and how to monitor cases on treatment.[1] Hence it is not surprising that the most commonly asked investigation in any laboratory is plasma glucose levels, which is usually more than three times any other biochemical parameter performed in a clinical chemistry laboratory. Accuracy of the results of plasma glucose estimation is paramount, and plasma glucose level consistency of a laboratory is usually considered as an index to the laboratory's quality. Most of the laboratories are following internal and external quality assurance programs to ensure accuracy of the results. National Accreditation Body of Laboratories insists that laboratories mention the 'Uncertainty of Measurement'.[2,3] in their results in order to educate the clinicians on the extent of possible error in the result. By adopting these measures, with improved instrumentation and the reduction in human intervention, the accuracy of the results generated in laboratories have seen significant improvement.

However, there are a lot of pre-analytical factors that are known to affect the quality of the input sample and this has a direct bearing on the final results. Many studies have been done to evaluate the magnitude of pre-analytical errors.[4,5,6,7] These studies suggested that nearly 40-70% of all the errors that occur in a laboratory setting are due to pre-analytical factors.[4,5] These errors usually pertain to the proper patient identification, order of draw of sample, the volume of sample collected, the storage and transport of samples, presence of haemolysis etc. Due to the significant increase in the awareness created about the pre-analytical errors, many laboratories

have now started adopting measures to reduce them.

However, there is a group of errors that are created by patients, and are usually "untold" and hence under-reported. The errors include the adequacy of patient preparation before giving the sample, the timing of the blood samples for plasma glucose (fasting and post prandial), circadian rhythm while collecting samples etc. Kackov et al[8] found that only 60% of the patients who gave their fasting sample were actually properly prepared for it. In another study by Senthilkumar et al[9], it was found that 20% of the Indian patients were not adhering to the instructions for giving plasma glucose sample although they were aware of the correct procedure. There are many a times when patients commit errors and do not report them while they are giving the samples. These errors made could be due to their ignorance, indifference or some other issues which make the sample given not truly representative. As these errors are not reported by the patient, they do not get reflected in the final result that is generated by the laboratory. The present study was undertaken to evaluate the quality of such 'untold errors' that had occurred in a sample that was provided to the laboratory and quantify them.

MATERIAL AND METHODS

The study was done at the OPD of a busy tertiary care hospital attached to a medical college. It was a descriptive study undertaken after obtaining the institution's ethical committee clearance. A total of 400 patients were included in this study.

Calculation of sample size

A pilot project was done on 100 subjects in whom the quality and quantity of patient related pre-analytical errors were evaluated in a questionnaire format. In the pilot study, the incidence of pre-analytical errors was found to be around 60%. This figure was used to calculate the population size which was found to be 384. Hence 400 cases were included in this study.

Inclusion criteria

Patients who had given the sample for plasma venous glucose estimation, both fasting (F) and post prandial (PP) and who agreed to participate in the study were included.

Exclusion criteria

The following were the exclusion criteria in the study:
a) People who had given similar test more than 5 times in the past were excluded from the study as it was felt that they would have got the required knowledge by then.
b) Hostile patients: patients who were giving inconsistent response to the questions asked or patients who appeared to be giving a tutored/fabricated answer to the questions asked were also excluded.

Data collection

The patients were interviewed after giving the PP sample. The patients had not reported of any kind of error while providing the sample, nor had the phlabotomist picked up any kind of pre-analytical error in the sample. Hence these samples would have been considered as a true representative sample. After starting the conversation as hospital representatives who were looking into patient satisfaction, gradually the questions were asked on how the samples for plasma glucose were collected. The interview was done by at-least two of the authors. The salient points looked into during the interview included:
a) How good was the fasting sample – Had the patient actually fasted properly before giving the sample?
b) The time duration between the F and PP sample
c) History of medication – did the patient take the regular medication as they were supposed to or were they omitted.
d) Exercise undertaken between the F and PP sample. The exertion undertaken by the patient was graded as follows:

No exercise: In case the patient was sitting in the sample collection room for the entire 2 hours.
Mild exercise: In case walking of less than 500 mts was undertaken by the patient.
Moderate exercise: Walking between 500 mts and 1 kilometre.
High exercise: Walking more than 1 kilometre.

The extent of exercise was calculated by asking the patient to tell about his movements during the two hours and then roughly evaluating the net distance travelled.

Adequacy of the PP sample was evaluated by two methods. One was by asking the patient the time when had given the F sample, the time when they finished the breakfast and then finding out the time the patient reported to have given his PP sample. At the sample collection room, all the phlebotomists were instructed to note the time of bleed in all the fluoride tubes. The patients sample tube was re-examined for the actual time of bleed. The difference between the two times along with the allowance for having breakfast (as quoted by the patient) was used to evaluate the exact PP time. Any difference beyond 10 minutes was considered as an error.

The results of the interview were then entered into a pre-defined format for data analysis. Each patient was interviewed by a pair of the authors and their consensus was then entered into the spread sheet which was used for final analysis.

RESULTS

A total of 400 patients were interviewed over a period of 2 months. On an average 10 patients were interviewed each day.

Demographic profile of the patients: There were 312 males and 88 females in the study. The average age of the patients included in this study was 43± 9.6 years. The youngest patient was 23 years of age and the oldest

patient in the study was 73 years of age. The indication for testing plasma glucose is shown in Figure 1.

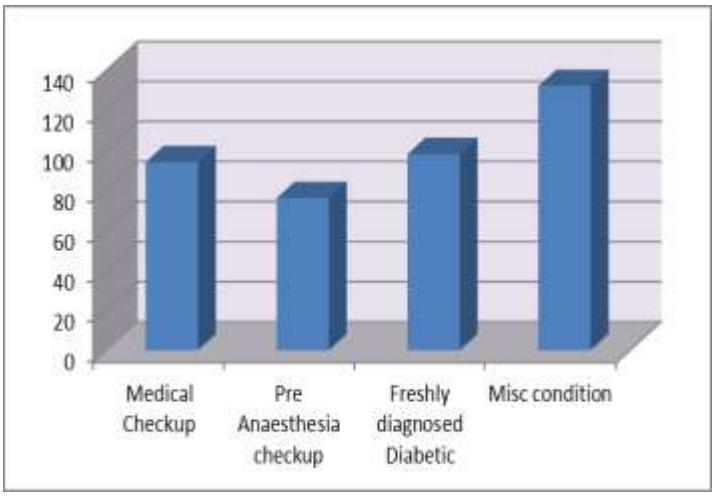

Figure 1: Indication of plasma venous glucose estimation

Fasting Sample timing

Table 1 shows the data of the quality of F sample. 256 cases had given a proper and true representative sample. There were 56 cases who had consumed bed tea/coffee or light snacks before submitting the F sample. There were 88 cases who had given the F sample beyond 1200 hours, although they claimed to be fasting. Assuming that their claim was true, such a sample would represent a fasting of at least 12 – 14 hours which would have initiated gluconeogenesis and made the sample non-representative. 18 patients who had submitted the F sample beyond 1200 h agreed to have had tea/coffee along with biscuits in the morning.

Table 1: Quality of Fasting sample provided in the study

Condition	n
Proper fasting sample	256
Having had something before giving fasting sample	74
Fasting samples collected beyond 1200h	88
Patients who gave samples beyond 1200 hrs and had consumed something before giving F sample	18

The PP sample timing

The timing between the F and PP sample was evaluated by two methods as discussed before. The results are shown in Table 2. From the data, it was apparent that 33.75% of the PP sample was not collected on time as it should have been. There were 3 patients who had given the PP sample within one hour of the fasting sample. During the interview however, only two patients had agreed to the fact that the second sample was given early as they had to use facilities of a common public transport and were constrained to give the PP sample earlier.

Table: 2 Timing of the PP sample.

PP sample	As reported by cases	As calculated from the primary sample tube
On time reported by patients	334	267
Not on time as reported by patients	56	133
Less than 1 hr	2	3
Less than 30 minutes	12	38
More than 30 min	39	79
More than one hour	3	3

Exercise

Figure 2 shows the nature of exercise undertaken before giving the PP sample. In this study only 9.75% of the cases were in the sample collection during the time between F and PP. More than 17% of the cases had undertaken moderate to high exercise.

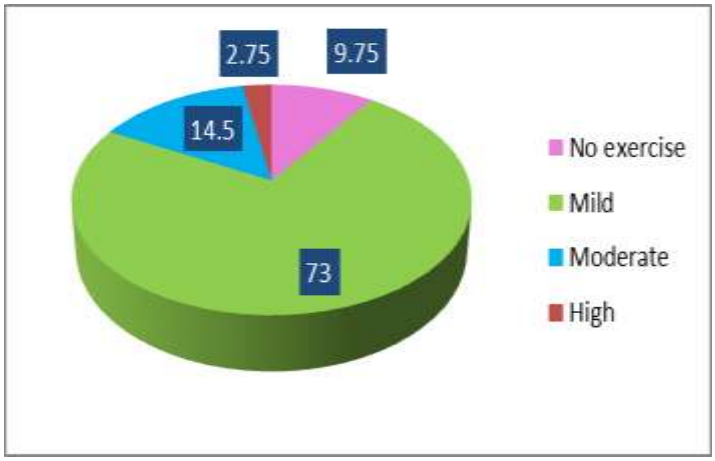

Figure 2: Exertion undertaken by the patients between F and PP sample

Medications

In this study, there were 94 cases that had recently been diagnosed with diabetes. They had not given blood samples for testing for more than five times and hence were included in the study. When we interviewed these 94 cases, we found that 21 patients (22%) did not take the medication as instructed with the impression that the PP sample had to be given without any medication.

Awareness about the test

As an added part of the study, we asked the subjects as to who informed them about how to give the sample for testing. We also asked them about what they understood on how the sample had to be given. A total of 263 participants said that the doctor had told them as to how to give the sample. There were 84 cases who were briefed by paramedical staff. The rest had got the information from friends or other patients. It also came to light that 15 cases did not know how to give the sample and had got the first information at the time of phlebotomy. Despite the fact that 85% of the cases were informed by medical/paramedical staff on how to give the sample for testing, 63% of the cases said that the PP sample needed to be given two hours after the fasting sample (not taking into account the time for breakfast) indicating that they did not have a clear perception on the exact procedure of providing samples.

Cumulative Errors

In this study the following conditions were considered as errors in giving the sample:

a) Fasting not proper – patient not fasting / giving the sample beyond 1200 hours
b) Timing of PP sample more/less than 10 minutes from the schedule time.
c) Patient having exerted during the study – we considered moderate and severe exercise only as errors as it was felt that they would result in tangible errors in the result.
d) Diabetic patients not taking medications during the test.

In all there could have been a maximum of four errors per patient (as noted in this study). Of the 400 cases in this study only 138 patients had given proper sample (mild exercise included). There were 167 cases that had only one error in the sample provided. Figure 3 shows the number of errors on the samples given for testing plasma venous glucose.

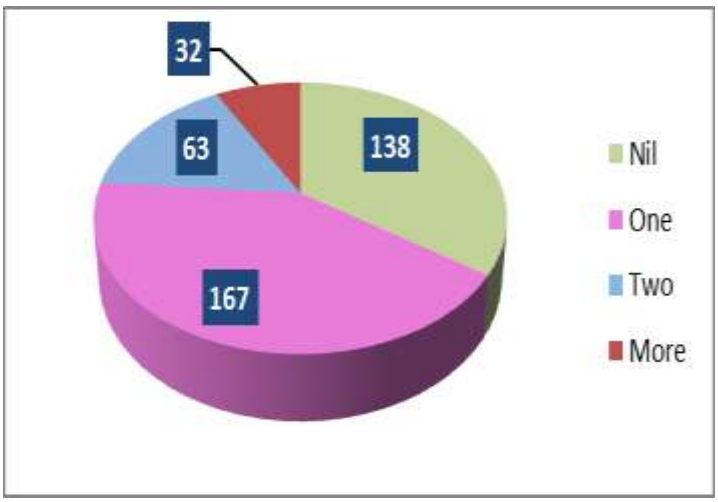

Figure 3: Number of errors per sample provided in the study.

DISCUSSION

Plasma glucose estimation is the most commonly asked test in any clinical laboratory. It is also the sample where the patient's participation in providing proper sample is essential. Hence we felt that while evaluating patient factors causing pre-analytical errors, a study on errors made by patients on this test would be appropriate. Most of the studies on evaluating the pre-analytical errors have been done using a questionnaire format. When we did a pilot sample using 100 patients, we realised that specific questions led to tutored answers, and we were not getting the true picture. Hence we changed our mode of interrogation to a friendly discussion and gradually elucidated the necessary finding from the patient without making them conscious about the fact.

Kackov et al[8] in their study reported that 40% of their cases were underprepared while they had reported for giving their fasting sample. Similarly in a study conducted at Tiruchirappalli, Senthilkumar et al[9] found that nearly 20% of the patients were not adhering to instruction on how to give the blood sample for glucose estimation. In our study, we found that only 34.5 % of the samples collected were without any kind of errors produced by the patient. This suggests that over 60% of the results generated had some kind of error made by the patient, a number which is really alarming. Nearly 36% of the patients had not given a proper fasting sample and as many as 133 out of 400 patients (22%) had given wrongly time post prandial sample. We also found that over 24 % of the samples had more than one error, a fact that could have a significant cumulative impact on the final result and the patient management thereof. Exercise is known to increase the stress hormones and have an impact on the results of the post prandial sample.[10] As many as 90% of all the patients had undertaken some form of physical exercise in-between the two samples with about 68 patients (17%) having done moderate to severe form of exercise (as define in the context of this study).

During our interaction with the patients, we realised that nearly 85% of the patients said that they were informed by health care people (doctors/paramedical staff) on how to give the blood for testing. However only 34% of the patients had given error-free sample.

The main reason for problems in the fasting sample was due to long distance the patient had to travel to reach our centre. It was also realised that few patients, after visiting an OPD and being referred to the test had decided to give the sample in the same visit. The errors on wrongly provided post prandial sample stemmed from the fact that it is very difficult for a person to wait in a place for two hours doing nothing. Either they visited other OPDs in the meantime or did some shopping/collect medicines and in the process reported late for the PP sample. Either ways, there was some kind of physical activity done by most of the patients which in itself was another pre-analytical error. It also came to light that there was no separate counter for the patient to give the post prandial sample, nor was there any priority treatment for patients giving the PP sample. As a result some of the patients had reported on time but their samples were collected late because they were waiting for their turn. Three patients had said that the post prandial sample was given within one hour of the fasting sample because they had to use the facilities of a common bus facility and could not wait for the full period of time.

The standard response at the phlebotomy room is that in case a pre-analytical error is noticed, the patient is asked to come the next day and repeat the test. The logistic problems involved in being asked to repeat the test is the main reason why patients may wilfully lie to the phlabotomist while giving the sample. This is well seen in the 74 cases that had consumed tea/coffee but did not report the same to the phlabotomist. The same fact applies to patients who come late to give the post prandial sample. Hence we feel that, while patient education on the consequence of providing wrong sample is essential, it may not eliminate occurrence of all the errors. A better method would be to encourage the patient to enumerate the errors made, and simply note them on the investigation form. When the results are generated, the laboratory as well as the clinicians would be aware of the kind of error that was present in the result and could interpret the results in that light.

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