



## Source of Patient Information: Physician or Laboratory? An Audit of Patient Information on OGTT protocol

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### Abstract

*The OGTT is an important tool for the diagnosis of Diabetes mellitus. Patients and clinical staff need to be aware of the potential for misdiagnosis when standard instructions regarding patient conduct before and during the test are not followed. Source of information regarding the protocol is an important aspect considering the complexity of patient preparation involved in Oral glucose tolerance test.*

**Keywords:** Oral glucose tolerance test (OGTT), preanalytical errors in OGTT, patient preparation, OGTT protocol.

### Introduction

The oral glucose tolerance test (OGTT) is widely used in the diagnosis of diabetes mellitus (DM), including gestational diabetes (GDM)<sup>(1)</sup> Following the development and successful implementation of high-quality analytical standards, analytical errors are no longer the main factor influencing the reliability and clinical utilization of laboratory diagnostics. Accordingly, lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93% of the errors currently encountered within the entire diagnostic process.<sup>(2)</sup>

Although ADA acknowledges OGTT as a valid way to diagnose diabetes and prediabetes, the use of the test for routine diagnostic purposes in clinical practice is limited in favour of fasting plasma glucose for several reasons, including inconvenience, greater cost and less reproducibility. OGTT involves time and strict patient compliance

and strict adherence to the protocol as laydown by report of committee on statistics of the American diabetes association in 1969<sup>(3)</sup>. According to this committee report, factors like patient preparation (duration of the fast, prior carbohydrate intake, medications), type and form of glucose administered to the patient, posture and activity during the waiting period are some of the factors that can affect the OGTT results. The dietary preparation for OGTT starts 3days prior to the procedure. The patient needs to take high carbohydrate diet, at least 150g per day for a minimum of three days. According to Randle's hypothesis<sup>(4)</sup> low carbohydrate diet is associated with improved glucose tolerance. This may lead to increased false negatives in the diagnosis of impaired glucose tolerance and diabetes. So the patient needs to be well informed about the prerequisites for OGTT before coming to the laboratory. Clinical experience shows lack of adherence to the protocol before and during a

GTT<sup>(5,6)</sup>. One of the reasons could be lack of effective communication to the patient. A majority of patients seems to receive complete instruction on the day of test from the phlebotomists.<sup>(7)(8)</sup> The recent report issued by the European commission shows that the level of communication between patients and their physicians was unsatisfactory and that the lack of physicians' time was identified as the main barrier to the effective communication.<sup>(9)</sup> However, there are limited studies on source of the information regarding the protocol. Hence this study was undertaken to test the hypothesis that there is lack of complete knowledge and adherence to the OGTT protocol by the patients while carrying out OGTT.

### Materials and Methods

This was a descriptive study.

A total of 275 subjects referred to phlebotomy for OGTT between September 2016 to 2017 were included in the study. Subjects belonged to urban and rural localities. The Study Group were selected through convenient sampling and included both Males and females in age group 18- 60 years. Informed consent was obtained from all the subjects after explaining the study to them.

### Inclusion criteria

- All adult subjects referred to phlebotomy for GTT who provided consent was included in the study.

### Exclusion criteria

- Subjects who are unable to comprehend the questions or have difficulties in understanding were excluded from the study.

Sample size was calculated based on previous study on pregnant woman<sup>(5)</sup> using the data published population proportion: 20%, expected population with low compliance to OGTT :40%. Calculated sample size is 250(alpha error 5% and power 80%)

A semi structured questionnaire was administered to each patient covering all aspects of the protocol.

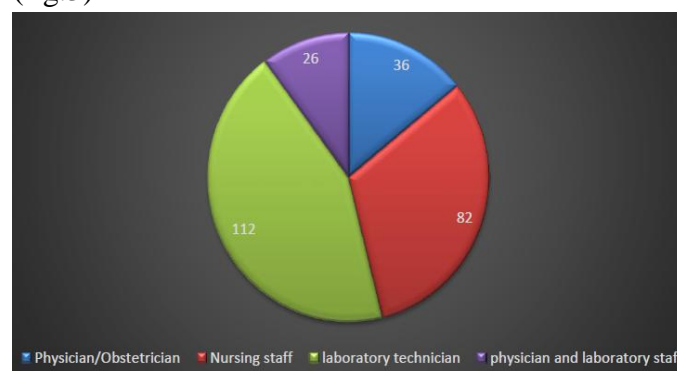
Statistics: Descriptive statistics were used. Variables have been represented in percentages and proportions.

The study was approved by Institutional Ethical Committee.

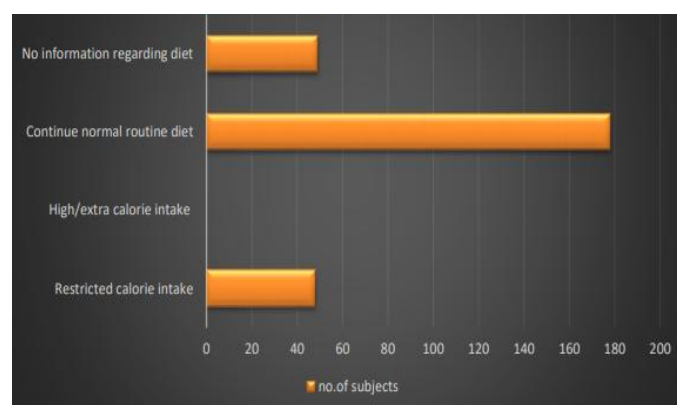
### Results

The study included 236 pregnant and 39 non pregnant individuals. The results of our study showed (fig.1) that the major source of information regarding patient preparation for Oral glucose tolerance testing to the patients was laboratory staff (40.7%) while treating physician played a limited role (14%) in this context.

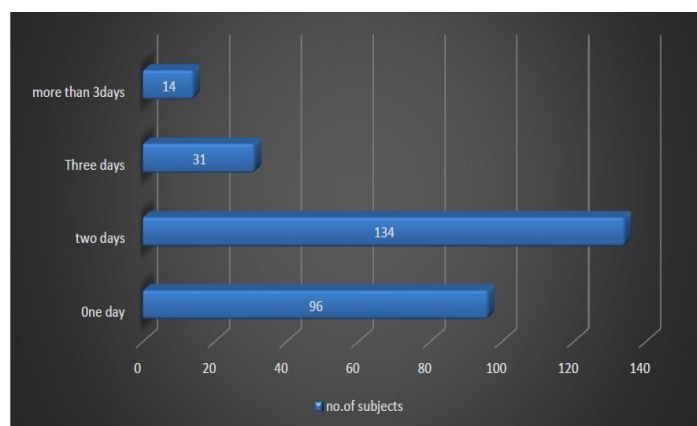
While 17.8% patients had no information regarding diet, 17% answered that they ate as little as possible, majority (64.7%) of the patients believed that they should continue their normal diet before coming to the test. (fig.2) However, the interval between physician visit and the day of the test also will be a contributing factor in dietary preparation. When patients were asked about the interval between physician consultation and actual procedure, it was found out that only 17% of patients have met their doctor 3 days prior to coming to the laboratory. (fig.3)



**Figure 1** Source of information regarding the protocol: only 14% (n=26+36)) of the patients were informed by their treating physicians



**Figure 1** Dietary intake prior to OGTT: 64% (n=178) patients continued their normal diet after their physician visit till the test.



**Figure 3.** Duration between physician visit and the test: only 17% of patients visited the doctor 3days prior to the test

### Discussion

The OGTT reflects the in vivo physiological response to a glucose meal and integrates the homeostatic response to a meal over time. Thus, the OGTT more accurately mirrors daily life. Despite the existence of detailed advice on how the GTT should be conducted,<sup>(1)</sup> there are still areas of ambiguity that require clarification. To ensure the quality of a sample it is necessary to minimize the preanalytical variability<sup>(10)</sup> which can be accomplished by a proper patient preparation for blood collection.

Proper patient's preparation plays a key role in OGTT and subsequently affects test results. Unfortunately, although it is well known that various factors such as diet, physical activity, stress, smoking or drinking certain beverages can affect OGTT results, patients remained poorly informed of the preparation for laboratory testing.<sup>(11)</sup>

In this study, we investigated who informs and when the patients are being informed about OGTT procedure before laboratory testing. Our results showed that patients who received instructions from their gynaecologist/physician were mainly informed about the need to be in the fasting state. Our study showed that only a small proportion of patients (13%) were informed by the physicians regarding the preparation prior to test. However, 83% of the patients knew that they were being tested for diabetes. A study by Patricija et al<sup>(6)</sup> on knowledge of OGTT protocol in pregnant women showed that

42% of the participants demonstrated high and 38% adequate level of knowledge about the OGTT procedure. Majority of participants were informed about the procedure by gynaecologist (56%). Our study was showing lesser percentage of patients being completely informed by their physician. (0.9%). The remaining percentage (99.1%) are being informed on the day of test by the laboratory personnel in the phlebotomy section.

The preparation for Oral glucose tolerance testing starts 3days prior to the actual laboratory procedure. It is recommended that there be a minimum carbohydrate intake of 150 gm presumably to allow for induction of enzymes of glucose utilizing pathways, for example, glucokinase, fatty acid synthase, and Acetyl CoA carboxylase.<sup>(12)</sup> Wilkerson et al<sup>(13)</sup> showed, that daily carbohydrate intakes of as low as 50 gm caused only slightly decreased glucose tolerance.

For each of the three days preceding the test provided that the subject was consuming a normal diet prior to this period. He found that glucose tolerance improved with a change from a low-carbohydrate/ high-fat diet to a high-carbohydrate/ low-fat diet. This improvement was affected neither by changes in the total calories, by the carbohydrate/ fat ratio in the diet, nor by the fat or protein content of the diet, but solely by the amount of carbohydrate in the diet. A study by conn et al<sup>(14)</sup> on requirement of carbohydrate in diet prior to OGTT showed there was a marked decrease in glucose tolerance on reduced carbohydrate intake and the subjects were falsely diagnosed as diabetics. In our study, only 17 % of patients have met the physician 3 days or more before coming to the laboratory. 83% of patients have met the physician less than 3days prior to the test. This may have affected proper evaluation of carbohydrate intake prior to testing and. One of the reasons for this aspect being taken for granted could be because, in general, the average Indian diet tends to be high in carbohydrates,<sup>(15)</sup> In India, 70-80% of total dietary calories are derived from carbohydrates present in plant foods such as cereals, millets and pulses.<sup>(16)</sup> In the CADI study, involving Indian physicians and

their family members, the average energy intakes from carbohydrates, total fats, and saturated fats were 56%, 32%, and 8% respectively. A study on Nutritional profile of Indian vegetarian diets by Krithiga et al<sup>(17)</sup> which was conducted on 6555 urban adults showed that average Indian vegetarian and non-vegetarian diet contained 431 and 426 g of carbohydrate respectively. But, these instructions might have affected the glucose tolerance values in patients who may be intentionally taking low calorie diet out of the concern of being diagnosed as diabetics or for weight loss.

### Conclusions

Based on our observations, it's seen that, complete instructions are received from the laboratory technician and often on the day of OGTT. Hence the preparedness of patients for OGTT in such situations becomes questionable. One of the reasons for this could be lack of manpower and hence lack of time to spend with the patients. To enable complete dissemination of information regarding pre-analytical preparation it may be ideal to develop written protocol in different languages in addition to verbal communication.

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