DIABETES OR IMPAIRED GLUCOSE TOLERANCE: DOES THE LABEL MATTER?

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Diagnosis has been considered a process of “labeling” with consequences that can be both positive (access to treatment) and negative (social rejection). The ultimate goal of making a diagnosis is to adequately inform the patient, thereby enhancing knowledge of the disorder, adherence to therapeutic advice, and the ability to manage illness effectively.

Impaired glucose tolerance (IGT) and diabetes mellitus (DM) are terms that differentiate two metabolic carbohydrate abnormalities. Establishing the optimum diagnostic levels for glycemic thresholds, however, depends on balancing the medical, social, and economic costs of labeling a patient who is not at substantial risk for developing complications, versus the corresponding costs of not diagnosing “true” cases (1).

Among patients who have alteration in metabolizing glucose, varying (in a controlled setting) the diagnostic criteria for diabetes mellitus and related carbohydrate disorders offers an opportunity to assess whether labeling, either as “IGT” or as “DM” influences patients’ knowledge of their disease, adherence to therapy, or mechanisms for coping and metabolic control. We used a clinical trial design to assess the effects of diagnostic labeling among participants randomly assigned to be informed that they had either IGT or DM.

Research Design and Methods

Participants were adults attending to a primary care clinic, with inclusion criteria of fasting glucose levels between 100 and 140 mg/dl, and glucose levels >140 mg/dl but <200 mg/dl two hours post 75 g of glucose. Glucose tests were obtained from routine evaluation. Patients had no previous diagnosis of IGT or DM, nor any additional comorbidity; they also had not ingested medicines that affect glucose metabolism. All patients volunteered to participate in the study. Written consent was not requested because the maneuver being tested involved only what was being said to the patient. The study was approved by the local Ethics Committee.

A sample size of 52 patients was calculated to detect a difference in compliance between the groups (1:1 ratio) of 30% (from 2.4 to 3.2 points in the scale), assuming 20% loss to follow-up, with a two-tailed significance test with an alpha level of 0.05 with 80% power. Diagnostic labeling was standardized via a leaflet containing general information on problems of glucose metabolism and how to manage them. Half of the leaflets (randomly) used the label “diabetes mellitus” and the other half used “impaired glucose tolerance”; the rest of the information was identical. The leaflets advised readers that problems associated with glucose are dynamic and could result in changes in diagnosis, depending on the phase of the illness. The specific variables studied were knowledge about the disease (2), compliance with treatment (2), quality of life (3), emotional functioning (3, 4), coping mechanisms (4), and glucose control.

The study was presented as a “Program for Glucose Problems.” Randomization was carried out in blocks of 13 subjects. The informational leaflets were in envelopes numbered from 1 to 52, corresponding to participants’ sequence in signing up for the study. One of the authors, not involved with clinical care of patients, did the “labeling.” He was also responsible for interviewing the participants and giving them the appropriate leaflet. No recommendations for drug therapy were given. Family physicians continued with patients’ treatment and were trained not to emphasize either diagnostic label.

At the first post-labeling visit, eight weeks after the baseline visit, the researcher reinforced the “label” as
described in the leaflet. The final evaluation was carried out 16 weeks after baseline. Both post-labeling evaluations were done by an evaluator blind to group assignment. Differences between groups were analyzed with Student’s t test, and changes within groups with paired t tests.

Results
We recruited 52 participants; 50 patients (25 in each group) remained until the end of the study, of which 42 were women. The mean level of glycemia post-load was 164 (standard deviation = 15.4) mg/dl, with a range from 141 to 193 mg/dl; the mean fasting glucose at the end of the study was 107 (standard deviation = 8.6 mg/dl). No statistically significant differences (data not shown) were found between the compared groups at the baseline evaluation, nor at the follow-up evaluation. In this context, our primary hypothesis—to detect enhanced compliance in the DM group—was not confirmed.

In comparisons within each group, however, patients who were labeled “impaired glucose tolerance” significantly increased their knowledge about their disease on the composite scale (see Table). Patients labeled as “diabetic” also increased their knowledge of the disease, as measured by both of the evaluations used. In addition, patients labeled as “diabetic” had decreased scores on emotional impact, avoidance-distraction, and the integration subscale (with lower ratings showing that a patient is more likely to accept the prospect of living with diabetes). For example, the mean score for avoidance-distraction decreased from 0.32 to 0.21 (p = 0.002) among the DM group.

Conclusions
Telling patients they had diabetes mellitus had a greater impact in changing some of their views about the disease than telling them they had impaired glucose tolerance. When treating patients, physicians should recognize that diagnosis (labeling) is a critically important component of the therapeutic process. In fact, patients can identify with a diagnostic label despite a lack of understanding regarding the details of their illness. Much of the tendency to adhere to treatment depends on whether patients accept the label placed on their illness (5).

This study has several strengths, including its randomized trial design, blinded evaluations, and measurements using previously validated instruments. Study limitations included a short time interval and relatively small sample size; and (although information provided to patients was standardized) it was not possible to control all information patients may have received. Overall, the results highlight the potential impact of how diagnostic information is provided to patients.

In summary, diagnosis, like measurement, assigns subjects to a category according to defined rules. Feinstein (6) had pointed out that the measurement of clinical phenomena must be done after answering key questions, e.g., what is the objective of the measurement? Does treatment differ depending on the diagnosis assigned? More recently, the STARD initiative (7) provided criteria for evaluation diagnostic accuracy. The current study emphasizes the additional consideration of how patients react to diagnostic information.
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<th>Impaired Glucose Tolerance (n=25)</th>
<th>Diabetes Mellitus (n=25)</th>
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<tr>
<td></td>
<td>mean</td>
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<tr>
<td>Glucose</td>
<td>105.0</td>
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<td>Glycosylated Hb</td>
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<td>3.53</td>
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<td>Avoidance-distraction.</td>
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<td>Tackling Spirit</td>
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<td>Passive-acceptance</td>
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<td>Integration Subscale</td>
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*P value for paired t-test of the differences between 1st and 2nd evaluations within each group. PAID = Problem Areas in Diabetes"