Abstract—Development of a diabetic patient database in order to study Cardiovascular Autonomic Neuropathy (CAN) using as a primary source, stress ECG is presented. The selected platform (ecgML) allows user-friendly environment to analyze and interpret graphs, signals and data. It also allows the ability to perform annotations and reports done by users from different fields. In order to feed the database, the input data is codify using MatLab. The database is composed by two populations: 1) Type 2 Diabetes mellitus group and 2) a control group with no medical history of cardiovascular disease. At the present, there are 62 records available from these two groups. The database also contains laboratory parameters, concurrent medical diagnoses reports verified by cardiologists and other clinicians, automatic annotations for each beat and trend series from parameters extracted from the ECG signals such as RR intervals and ST segment measurements. All this information will become very useful for CAN investigations.

I. INTRODUCTION

One serious complications of diabetes is Cardiovascular Autonomic Neuropathy (CAN). The CAN results from damages on the autonomic nerve fibers that innervate the heart and receptors of blood vessels, leading to a disorder in heart rate control and vascular dynamics [1]. Heart disease expressed as myocardial infarction and stroke is the main cause of death among type 2 diabetes patients. This pathology is the sixth cause of death in Venezuela [2].

Diverse studies carried out in patients with CAN revealed a lack of physiological response of the heart to several stimulus of physical stress, such as: exercise measured by heart rate and blood pressure [1] [3]. It has been shown that CAN could be diagnosed in the early stages of diabetes, since there is an inverse relationship between the severity of the CAN and heart rate variability. These findings are also associated to the decrease in cardiac output, systolic dysfunction and alteration of the diastolic ventricular time [3].

The creation of this database is framed within the Diagnostic and Modelling of Diabetic Cardiac Neuropathy Project (DICARDIA). The goal of this project is to achieve a better understanding of the mechanisms underlying CAN and developing methods for its early diagnoses. In this work, we describe the first stage of the project, developing a database for the study of CAN in diabetic patient. The database was created using as primary source, the stress tests performed at the Hospital Universitario de Caracas (HUC) on a daily basis and using the main features from ecgML [4].

II. METHODS

Some CAN symptoms can be described as: resting tachycardia, low heart rate variability during deep inspiration, limited exercise tolerance, prolonged QT interval, abnormal circadian pattern of blood pressure and orthostatic hypotension [5]. Other factors such as drug consumption, lifestyle and age can play an important role in the natural history of the disease. Diverse studies published in this area emphasize the importance of making a suitable design in the clinical protocol to obtain an appropriate selection of signals and parameters for the database to address this common chronic complication of diabetes [6]. Exercise ECG was chosen because it is a non invasive and inexpensive routine investigation broadly performed in a daily basis in most clinical centers. It is also possible to define fixed periods of time during the procedure for selected maneuvers that would aim to stimulate the autonomic nervous system. Moreover, continuous and non-continuous signals such as ECG, heart rate and blood pressure in different postural conditions can be acquired and analyzed. This is very useful, in terms of modelling systems, since it provides an opportunity to challenge a certain system with a set of inputs and perform inferences upon these responses at different stages [7]. Additionally, laboratory
parameters such as fasting glucose and hemoglobin A1C from participants were collected and added to the database.

A. Materials and Methods
Population was divided in two groups:
- Type 2 Diabetes Mellitus group: Patients with type 2 Diabetes mellitus diagnosis according to the American Diabetes Association.
- Control group: Healthy participants with no past medical history of cardiovascular or neurological disease and under no drug regimen.

Exclusion Criterion:
- Walking disability.
- Clinical or metabolic decompensation of the Diabetes.
- Recent history of an acute coronary syndrome.
- Other causes of autonomic dysfunction.

This research was approved by the Ethics board committee at the HUC. All volunteers signed the informed consent form to participate in this trial. The clinical protocol was controlled and supervised by the clinical staff from the department of cardiology at the HUC.

B. Data Records
- Demographic data was obtained by direct interview to patients and volunteers.
- Records of laboratory parameters: 14 hours fasting prior laboratory blood test.
- Stress ECG tests were performed on a treadmill using the Bruce Protocol until linear estimation of maximum heart rate was reached based on age and gender, following “The American Heart Association” guidelines [8]. Digital records of the ECG were acquired by the AT Plus system. It is composed by an ECG acquisition module, a microcomputer PC, an Ergocid Plus application, a Laser printer and a Ergometer [9].

Each record of 12 lead ECG, digitized with a sampling rate of 500 Hz, 12 bits resolution, dynamic range of ±5 mV, and with duration period between 15 and 25 minutes.

C. Database Description
The platform chosen for this database was ecgML. The ecgML came up as an alternative for existing formats in terms of structured organization, representation, and associated costs, simultaneously providing to the reader information about the records and waveform of the ECG. The navigator can be acquired free from the Internet, since it is an open-source software feasible to use with Java [4].

The ecgML platform allows visualization of the raw ECG signal and data demographic information as well as clinical data from the patient. The main menu bar is at the top of the window, including File, Windows and Help. The File menu allows to open and close the XML files. Windows menu allows to open recent files and Help menu shows the ecgML version.

III. RESULTS
A. Population
Continuous data are presented as mean ± standard deviation (SD), nominal parameters are presented as frequency.
Characteristics of the populations recorded are shown in table I. Diabetic Population and Control Group contain 51 and 11 records respectively. In table II parameters of stress ECG obtained from medical report are shown.

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Diabetic (mean±SD)</th>
<th>Group Control (mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>57±10</td>
<td>50±6</td>
</tr>
<tr>
<td>Man</td>
<td>25</td>
<td>8</td>
</tr>
<tr>
<td>Women</td>
<td>26</td>
<td>3</td>
</tr>
<tr>
<td>Smoking history</td>
<td>47 non</td>
<td>9 non</td>
</tr>
<tr>
<td></td>
<td>4 yes</td>
<td>2 yes</td>
</tr>
<tr>
<td>Weight</td>
<td>73±15</td>
<td>81±20</td>
</tr>
</tbody>
</table>

B. Database
The data was input into the database manually taken from medical records. This form collects the demographic data from the interview and laboratory results. Also, it contains the stress ECG results and the clinical diagnose. These data and the raw ECG file are saved in the ecgML platform. Then, they are represented graphically in a hierarchal structure in XML language (Fig. 2).
In the “Structure Pane” using ecgML (Fig. 2), nodes marked by a rectangle allow the handling of any specific information like a particular attribute, which is used to indicate demographic parameters or any other required information. The “Waveform Pane” shows an ECG signal of all acquired channels and corresponding with the data displayed on the structure pane.

This feature will let users to select the desired signal. A database generator was developed using Matlab®. This database generator is composed by a graphic interface template that contains two applications: a database generator and a report generator.

The database generator invites the user to supply the demographic and clinical data of the patient, giving as a result a code in XML language, which can be visualized using ecgML in hierarchal order. All information related to the patient and the ECG signal with its corresponding annotations is displayed (Fig. 3). Annotations were obtained using an algorithm developed in our research group [10].

The objective of the report generator is to display a friendly interface for the investigator to access ECG data, RR and ST segment trends. The report generator also allows to perform annotations on the ECG signal. In (Fig. 4), raw ECG (duration: 2s), RR interval series and ST segment trends are shown, additionally the scroll bar can forward and backward ECG display. These features are useful to identify ECG waveform changes and to provide aid in the diagnosis of certain pathologies.

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IV. DISCUSSION

A database for better understanding the mechanisms underlying CAN has been developed.

There are 62 records available from diabetic and control patients. The database contains the clinical diagnoses report, verified by certified cardiologists and the automatic annotation for each beat. It allows trend series extracted from several parameters analyzed from the ECG signal such as: RR interval and ST segment changes.

The database is available on a DVD format, and it contains the information of both generators (database and report generator in XML format and PDF document). Additionally, there are records of the acquired ECG by ERGOCID AT Plus with its respective reader, in this way the user can access the raw ECG data for further analysis.
The parameters extraction from RR interval series will allow to study heart rate variability for the assessment of chronotropic response in diabetic patients.

The selected platform ecgML provides a single interface with a friendly environment to share graphs, data, annotations and reports that can be used by different users and purposes. For the clinical staff, a digital report format was generated. Also, QRS delineation has been made to obtain annotations for RR interval and ST segment trends.

The clinical protocol proposed is simple and noninvasive, ecgML is friendly and flexible. The stress test ECG provides an important amount of information from different physiological conditions. These factors will permit to increase the population to evaluate also diabetic patients in different stages of their disease.

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REFERENCES