Tele-electrocardiography and Bigdata: The CODE (Clinical Outcomes in Digital Electrocardiography) Study

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Abstract

Digital electrocardiographs are now widely available and a large number of digital electrocardiograms (ECGs) have been recorded and stored. The present study describes the development and clinical applications of a large database of such digital ECGs, namely the CODE (Clinical Outcomes in Digital Electrocardiology) study.

ECGs obtained by the Telehealth Network of Minas Gerais, Brazil, from 2010-17, were organized in a structured database. A hierarchical free-text machine learning algorithm recognized specific ECG diagnoses from cardiologist reports. The Glasgow ECG Analysis Program provided Minnesota Codes and automatic diagnostic statements. The presence of a specific ECG abnormality was considered when both automatic and medical diagnosis were concordant; cases of discordance were decided using heuristisc rules and manual review. The ECG database was linked to the national mortality information system using probabilistic linkage methods.

From 2,470,424 ECGs, 1,773,689 patients were identified. After excluding the ECGs with technical problems and patients <16 years-old, 1,558,415 patients were studied. High performance measures were obtained using an end-to-end deep neural network trained to detect 6 types of ECG abnormalities, with F1 scores >80% and specificity >99% in an independent test dataset. We also evaluated the risk of mortality associated with the presence of atrial fibrillation (AF), which showed that AF was a strong predictor of cardiovascular mortality and mortality for all causes, with increased risk in women.

In conclusion, a large database that comprises all ECGs performed by a large telehealth network can be useful for further developments in the field of digital electrocardiography, clinical cardiology and cardiovascular epidemiology.

Introduction

Cardiovascular (CV) diseases are the leading cause of death worldwide and, in 2015, caused 18 million deaths worldwide (1). The electrocardiogram (ECG) is an important diagnostic tool for this group of diseases, as well as an ancillary method for many others, with established value in the diagnosis, prognosis and therapeutic monitoring of several CV diseases. Most of the knowledge on the value of the ECG has been obtained by clinical observations, correlations of ECG findings with abnormalities observed in imaging or pathological studies, or derived from cohort studies. The availability of digital ECGs, in the last few decades, has permitted the development of digital ECG databases (2), that have been used for several purposes, such as to evaluate the prognosis of ECG abnormalities in communities and specific populations, to study genetic determinants of arrhythmias and ECG abnormalities and to determine the natural history of diseases. Databases have also been developed for serving as a reference for electrocardiographic computer measurement and diagnostic programs (3) and to develop new methods or algorithms for ECG analysis (4).

Most of these databases do not have the amount of data which is now available, with many of them being developed in the dawn of the digital era. Digital ECG machines have now become widely available and large number of exams are being stored in hospital and health services in different countries and are often linked to electronic health records or administrative databases. This huge amount of data - *big data*, analyzed by methods recently developed in the machine learning and data mining fields, may allow the recognition of hidden patterns that were not detected in the past by traditional statistical methods. This may serve for the development of new analytical tools, opening up a world of new possibilities (5). We hypothesize that a large, annotated, database of digital ECGs, obtained in the community and linked with hospitalizations and death obtained from health or vital records will constitute an electronic cohort able to provide clinically useful prognostic information, as well as a better classification method for standard 12-lead ECG. The aim of the CODE study is to develop such a dataset and conduct studies on prognosis and classification of electrocardiograms. The present report i) describes the development of a large database of digital ECGs linked to mortality data, ii) shows initial results and iii) discusses its challenges and potential applications.

History of development

In 2005, with the support of the regional research agency of the state of Minas Gerais (FAPEMIG), a project to study the feasibility and cost-benefit of developing a tele-ECG service was implemented in 82 towns of this state, in Southeast Brazil (6, 7). A digital ECG machine able to send ECG tracings to a central hub was provided to primary care facilities in those small towns. Cardiologists from 5 University hospitals in different parts of the state provided the ECG report which was sent back to the computer of the primary health care center. The system proved to be feasible, with high utilization rates, and was cost-effective (6, 7).

The tele-ECG system gave origin to the Telehealth Network of Minas Gerais (TNMG), a collaborative network of seven public universities in the state of Minas Gerais, Southeast Brazil, coordinated by the University Hospital of Universidade Federal de Minas Gerais (8). The TNMG provides telehealth services in several different fields of health, as tele-diagnosis (ECG, retinography, among others) and teleconsultations (synchronous or asynchronous second opinion in specific cases), as well as mHealth and tele-educational activities (8). It has expanded progressively to other towns of the state of Minas Gerais and currently covers 814 municipalities in

Minas Gerais, mainly in primary health care (PHC) centers, but also in emergency departments, ambulances and hospitals. More recently, in 2017, as part of a program of the Brazilian Ministry of Health, it also began to provide tele-ECG services for other Brazilian states in the Amazonian and northeast regions. Over 4 million tele-electrocardiogram (ECG) reports and over 124,000 teleconsultations have already been performed (as of April 2019), as well as tele-retinography, Holter and tele-education activities, with quality assured by regular audits.

The CODE (Clinical Outcomes in Digital Electrocardiography) study is an initiative to consolidate and organize the database of digital ECG exams of the TNMG, linking it to the public databases of the Mortality and Hospitalization Information Systems. It was hoped that the consolidated database would be useful for multiple purposes, including the evaluation of epidemiological and prognostic significance of ECG findings and the development of new methods of automatic classification of ECG abnormalities, using both conventional statistical methods and new machine learning techniques. The project was approved by the Research Ethics Committee of the Universidade Federal de Minas Gerais.

Description

All 12 lead ECGs analyzed in this study were obtained by the TNMG, using a Web application built on the Java programming language (6, 8). ECGs were recorded using an electrocardiograph manufactured by Tecnologia Eletrônica Brasileira (São Paulo, Brazil) – model TEB ECGPC - or Micromed Biotecnologia (Brasilia, Brazil) - model ErgoPC 13, from 2010 to 2017. Tracings obtained by these ECG machines were sent to central servers by internet, using the web application developed in-house. The duration of the ECG recordings was between 7 and 10 seconds sampled at frequencies ranging from 300 to 1000 Hz, due to specific features of electrocardiograph machines used. All ECGs performed by the TNMG were interpreted by a team of trained cardiologists using standardized criteria (9), in order to generate an ECG report, which was prepared as free text. ECGs were periodically audited to recognize medical errors and discordant interpretations, in order to guarantee quality and uniformity of cardiology reports.

A hierarchical free-text machine learning algorithm was used to recognize specific ECG diagnoses among these reports. A list of specific diagnoses was created (CODE classes), according to international guidelines (9). First, the text was preprocessed by removing stop-words and generating n-grams. Then, the Lazy Associative Classifier (LAC) (10) was used, which was built with a 2800-sample dictionary manually created by specialists based on texts from real diagnoses. The final report was obtained by inputing the LAC results to a decision tree for class disambiguation. The decision tree was trained using the original dataset. The classification model was tested on 4557 medical reports evaluated manually, with the following macro F1 scores achieved: (1) 1d AV block = 0.729; (2) RBBB = 0.849; (3) LBBB = 0.838; (4) Sinus Bradycardia = 0.991; (5) AF = 0.993; (6) Sinus Tachycardia = 0.974.

All ECG tracings in the database were also analyzed by the Glasgow 12-lead ECG analysis program (release 28.4.1, issued on June 16th 2009), exporting the automatic diagnosis, codified by both Glasgow Diagnostic Statements (11) and Minnesota codes (12). Correspondences between CODE classes, Glasgow Diagnostic Statements and Minnesota codes were mapped. For the CODE database, the presence of a specific electrocardiographic diagnosis was considered automatically when there was agreement between the diagnosis extracted from the cardiologist report and the automatic report from Glasgow Diagnostic Statements or

Minnesota code. In cases where there were discordances between medical report and one of the automatic programs, a manual revision was done by trained staff.

The electronic cohort was obtained linking data from the ECG exams (name, sex, date of birth, city of residence) and those from the national mortality information system, using standard probabilistic linkage methods (FRIL: Fine- grained record linkage software, v.2.1.5, Atlanta, GA). After the linkage, the data was anonymized for storage.

The data is stored in a PostgreSQL database with the most important fields for analysis being: patient, exam data, ECG exam tracing, lead signals, text report, CODE study diagnosis, Glasgow Diagnostic Statements, Minnesota code classes and data from the death declaration. Table 1 describes some of the attributes available in the most important tables.

Table 1 – Main variables and data stored in the CODE dataset

Patient	Patient ID, sex, age, address, town
Clinical History	Comorbidities and drugs in use (self-reported)
Exam	Exam ID, date, health care center
Exam tracing	Tracing number, heart rate, muscle filter, speed, sampling rate, sensitivity
Lead signal	register number, 12 lead signal
ECG measurements	P duration, P frontal axis, PR interval, QRS duration, QRS frontal axis, QT interval, T duration
Text report	Cardiologist report
Minnesota code class	Minnesota code and description
Glasgow Diagnostic Statements	Glasgow Diagnostic Statement codes and description
CODE class	CODE ECG diagnosis
Mortality data	Date, place (town) and cause of death (ICD-10)

Clinical role

From a dataset of 2,470,424 ECGs, 1,773,689 patients were identified. After excluding the ECGs with technical problems and patients under 16 years old, a total of 1,558,415 patients were included for analyses. The mean age was 51.6 [SD17.6] years with 40.2% male (Table 2). The overall mortality rate was 3.34% in a mean follow-up of 3.7 years. The resultant dataset has several potential applications, both for technical and clinical-epidemiological studies. Two studies already presented in congresses (16, 17) are highlighted.

	n	%
Comorbidities		
Diabetes	101,470	6.51
COPD	11,266	0.72
Chagas disease	34,590	2.22
Dyslipidemia	60,590	3.89
MI	11,604	0.74
Hypertension	492,637	31.61
Smoke	108,814	6.98
ECG Abnormalities		
AF	20,782	1.33
1dAVb	20,848	1.34
LBBB	20,610	1.32
RBBB	37,413	2.40
SB	24,565	1,58
ST	34,369	2,21
WPW	1,093	0.07

Table 2: Prevalence of comorbidities and ECG abnormalities from a total of 1,558,415 patients. COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; AF, Atrial fibrillation; 1dAVb, first degree Atrioventricular block; LBBB, left bundle branch block; RBBB, right bundle branch block; WPW, Wolff-Parkinson-White; SB, sinus bradycardia; ST, sinus tachycardia.

Example 1: Training of Deep Neural Networks for Automatic ECG diagnosis

There is a lot of excitement about how machine learning, and more specifically, deep neural networks (DNNs) might improve health care and clinical practice.(5, 13) DNN models can benefit from having large datasets and produce high accuracy models (13). This has allowed these models to achieve striking success in tasks such as image classification (14) and speech recognition (15). Our dataset has been used to train a DNN to automatically detect 6 types of ECG abnormalities - right and left bundle branch block (RBBB and LBBB), 1st degree AV block (1dAVb), atrial fibrillation (AF), sinus tachycardia and bradycardia (ST and SB) - which were considered representative of both rhythmic and morphologic ECG abnormalities (16). We used a convolutional neural network similar to the residual network (17), but adapted to unidimensional signals. We have adopted the modification in the residualblock proposed in (18). The network consists of a convolutional layer followed by four residual blocks with two convolutional layers per block. The convolutional layers have filter length 16, starting with 4096 samples, and 64 filters for the first layer and residual block and increasing the number of filters by 64 every second residual block and subsampling by a factor of 4 every residual block.

We compared the performance with cardiology and emergency resident medical doctors as well as medical students and, considering the F1 score, the DNN matches or outperforms the medical residents and students for all abnormalities (see Table 3). These results indicate that end-to-end automatic ECG analysis based on DNNs, previously used only in a single-lead setup (19), generalizes well to the 12-lead ECG.

This is an important result in that it takes this technology much closer to standard clinical practice.

	Precision (PPV)				Recall (Sensitivity)				Specificity				F1 score			
	DNN	cardio.	emerg.	stud.	DNN	cardio.	emerg.	stud.	DNN	cardio.	emerg.	stud.	DNN	cardio.	emerg.	stud.
1dAVb	0.893	0.905	0.639	0.605	0.893	0.679	0.821	0.929	0.996	0.997	0.984	0.979	**0.893**	0.776	0.719	0.732
RBBB	0.872	0.868	0.963	0.914	1.000	0.971	0.765	0.941	0.994	0.994	0.999	0.996	**0.932**	0.917	0.852	0.928
LBBB	0.968	1.000	0.963	0.931	1.000	0.900	0.867	0.900	0.999	1.000	0.999	0.997	**0.984**	0.947	0.912	0.915
SB	0.833	0.833	0.824	0.750	0.938	0.938	0.875	0.750	0.996	0.996	0.996	0.995	**0.882**	**0.882**	0.848	0.750
AF	0.800	0.769	0.800	0.571	0.923	0.769	0.615	0.923	0.996	0.996	0.998	0.989	**0.857**	0.769	0.696	0.706
ST	0.897	0.968	0.919	0.882	0.972	0.833	0.944	0.833	0.995	0.999	0.996	0.995	**0.933**	0.896	0.932	0.857

Table 3: Performance of the DNN for detecting 6 types of abnormalities. Scores of the DNN are compared with the average performance of: i) 4th year cardiology resident(cardio.); ii) 3rd year emergency resident (emerg.); and, iii) 5th year medical students (stud.). (PPV = positive predictive value). The gold standard was a consensus of 3 certified cardiologists.

Example 2: Evaluation of the prognosis of atrial fibrillation

By using the large cohort of the CODE study, the risk of mortality in men and women with AF was evaluated in a preliminary report (20). Only the first ECG of each patient was considered. Patients under 16 years were excluded. Hazard ratios (HR) for mortality were adjusted for demographic and self-reported clinical factors and estimated with Cox regression. AF was an independent risk factor for all-cause mortality (HR 2.10, 95%CI 2.03-2.17) and cardiovascular mortality (HR 2.03, 95%CI 1.81-2.27). In multivariable analysis by sex, adjusted for age and comorbidities, women with AF had a higher risk of death for all causes (HR 2.59, 95% CI 2.47–2.73) than men with AF (HR 1.83, 95% CI 1.74–1.91). It was concluded that AF was a strong predictor of cardiovascular and all-cause mortality in a primary care population, with increased risk in women.

Limitations

Data storage and database structural changes over time

Although the TNMG has been in service since 2006, it was only possible to recover tracings obtained after 2010. ECGs acquired before 2010 were stored in proprietary format (.EWC) or as images (.JPG) by the ECG system used at that time. The analysis of these older tracings would be very useful to evaluate the long-term prognostic meaning ECG abnormalities observed in the first ECG.

Noise and absence of signal

Approximately 2.5% of the exams had low quality ECG signals and were classified as unsatisfactory for medical reporting and excluded of the preliminary analysis showed in this article. To recognize those low quality tracings, an algorithm to evaluate the quality of the ECG tracing was developed, to be used in the future analysis. It calculates the signal-to-noise ratio of the ECG tracing (21), and classifies the exam as reportable or non-reportable, due to either overall poor signal quality or absence of signal.

Labelling issues

Labelling all types of ECG abnormalities in the whole dataset has been challenging. Both the automatic coding using the software of the University of Glasgow and the medical diagnosis, extracted through natural language process (9), are imperfect. Thus, a large number of tracings had to be reviewed manually by medical students, under the supervision of an experienced cardiologist. This process was possible to be done in the first phase of the study, in which studied ECG abnormalities had prevalence of less than 3%. More common ECG findings, such as non-specific alterations in ventricular repolarization and left atrial abnormality, will be difficult to classify in the whole dataset using this same procedure and new approaches are needed.

Future Work

The current dataset opens up several possibilities for future work. We are currently proceeding on an extended version of the CODE dataset, to include patients with ECGs recorded from 2006 to 2010 and after 2017, as well as on further linkage to the hospitalization database of the public health system (*Sistema de Informações Hospitalares – SIM*). It would allow not only the prediction of the risk of death, but also of relevant medical procedures, such as pacemaker implantation and cardiac revascularization.

From May 2018 on, all exams have been analyzed using a new reading software, with several new tools to facilitate the work of the cardiologist. One of these new features is that the cardiologist should choose which ECG classes he/she considered are adequate to the diagnosis for a specific exam, among a list of ECG CODE classes, as listed below, instead of using free text, as in the past. Thus, in more than 600,000 exams reported since then, we have the class of diagnosis annotated directly from the specialist, without using natural language processing or the heuristic rules we used for annotation of the dataset since now. We will use this more easily and precisely annotated dataset to apply the deep learning for classification of the full list of ECG abnormalities. This could, in the future, provide a new technology to be used in automatic classification of 12-lead ECG tracings that could be integrated in the telehealth system or even embedded in ECG machines

This tested and accurate algorithm for classification of all classes of ECG abnormalities could be used to complete labelling of the whole dataset, a challenge we described in the limitations chapter. A larger dataset, from 2006 on, linked to the hospitalization and mortality date, would allow the development of new prognostic studies on the risk of specific ECG abnormalities in this cohort highly representative of the general population, as well as new risk scores. New ECG indexes can be generated also with the application of machine learning methods to recognize those with higher risk of death, or appearance of new ECG abnormalities, as incident atrial fibrillation and bundle branch block.

Further studies can also include the use of methods developed for recognition of established markers of cardiovascular risk, such as left ventricular systolic dysfunction (22), allowing recognition of those subjects whose ECG suggested that they could benefit from having an echocardiogram recorded. This routine, if proved effective, could be implemented in the telehealth network and improve the ability of the health system to use resources more cost effectively, especially in resource-constrained regions.

Conclusion

Electrocardiography is now well over a 100-year-old method, with an established role in the care of patients with documented or suspected cardiovascular diseases. The availability of large databases, linked to other clinical and vital information, as well as new methods of analysis can further increase our knowledge in the role of electrocardiography in clinical practice and open new applications of its use. Thus, the CODE dataset, which is a large database that comprises all ECGs performed by a large telehealth network, can be useful for further developments in the field of digital electrocardiography, clinical cardiology and cardiovascular epidemiology.

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